Targis® System

CoolWave® Control Unit

User Manual

UROLOGIX®

Part Number 250023-001 Rev G

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Patient Safety Summary

This patient safety summary is an overview of the key patient safety information provided in the CoolWave® Control Unit User Manual. Please refer to the user manual to obtain all safety information pertaining to the use and operation of the CoolWave Control Unit.

- The treating physician should be present at all times during treatment.
- Perform an enema 1 to 2 hours before treatment or per physician instructions. An enema is mandatory.
- It is critical that, throughout the patient's treatment, the treating physician verify the correct position of the microwave catheter and the rectal unit. Patient safety is at risk if the following simple and straightforward safety check procedures are not correctly observed.

Safety Checks

1. Throughout the duration of the treatment, verify that the position mark on the catheter remains at a fixed distance from the penile meatus.
2. It is strongly recommended that at least every 5 - 10 minutes of the treatment, the correct position of the location balloon and the rectal unit is checked.
3. Always immediately check microwave catheter and rectal unit placement if the patient complains of any abnormal or sudden increase in pain. Pause the treatment if the patient complains of serious pain.
4. Observe the treatment parameters for sudden changes in readings, especially decreases in temperatures that might indicate a sensor has moved from its previous position.

Warnings

- The Cooled ThermoTherapy™ Procedure must not be initiated without assurance that the microwave catheter is properly positioned in the patient. **The correct positioning of the catheter must always be checked by ultrasound imaging prior to commencing treatment. Improper placement or orientation of the microwave catheter may lead to procedure failures or heating damage of nontarget tissues such as the bladder neck, external sphincter, or penile urethra.**
- Do not underinflate or overinflate the microwave catheter balloon. Underinflation can cause the microwave antenna to be misplaced in the prostate, affecting the external sphincter or penile urethra. Overinflation may result in balloon malfunction and possible improper positioning of the microwave antenna.
- The rectal unit must be positioned and inflated properly to ensure correct temperature sensing.

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1 Systems Description

1.1 Notice

The information contained in this manual is subject to change. This manual does not necessarily address all safety concerns associated with the Urologix® CoolWave® Control Unit.

The CoolWave Control Unit is intended for use only by qualified medical personnel. Federal (USA) law restricts this device to sale by or on the order of a physician trained and/or experienced in the use of this device as outlined in the required training program.

Medical equipment, however sophisticated, should never be a substitute for the human care, attention, and critical judgment that only trained healthcare professionals can provide.

1.2 Safety symbols and definitions

The following safety symbols are used throughout this manual. Familiarize yourself with each symbol and its meaning before using this equipment. You can find additional symbols associated with the CoolWave Control Unit in *Section 5.3, Description of symbols*.

Safety Symbol	Definition
Note	A note indicates important information that helps you operate the CoolWave Control Unit or use the disposable devices.
Caution	A caution contains instructions that must be followed to avoid a possible malfunction of or damage to the equipment or its connected devices. Do not proceed beyond a caution sign until the indicated conditions are fully understood and met.
Warning	A warning contains important information about possible danger to you or the patient. Do not proceed beyond a warning sign until the indicated conditions are fully understood and met.
Instruction Manual	The instruction manual symbol is displayed on the product when it is necessary for you to refer to the CoolWave Control Unit User Manual (this document).

Table 1-1. Safety Symbols and Definitions

1.3 User Manual Overview

This manual combines technical reference material as well as information on how to use the CoolWave Control Unit.

Notes:

- For information regarding the contents of this manual, please call Urologix Customer Service at 1-888-229-0772.
- Read this manual before operating the CoolWave Control Unit.

Section 1: System Description provides an overview of the CoolWave Control Unit equipment. This section also provides important notes about using the CoolWave Control Unit including information on installation, use environment, equipment connections, equipment testing, and safety instructions.

Section 2: Treatment Session Setup describes how to prepare the patient, prepare the CoolWave Control Unit, install the coolant bag, and insert the microwave catheter and the RTU (rectal unit).

Section 3: Treatment Instructions provides instruction on how to use the CoolWave Control Unit from logging into the CoolWave Control Unit to beginning and ending a Cooled ThermoTherapy™ procedure. You will also find information on how to change system settings, handle system errors, and work in demonstration mode.

Section 4: Equipment Maintenance presents information on post-treatment cleaning procedures and storage instructions. You will also find information on how to move and ship the CoolWave Control Unit. Finally, this section discusses how to maintain the equipment, though some maintenance requires a Urologix trained service representative.

Section 5: Appendix includes a troubleshooting guide, a flowchart of the treatment screens, a description of the symbols used in the manual and on the labels, an overview of the Patient Comfort Kit, and a glossary of terms used in CoolWave Control Unit literature.

1.4 Precautions

Only those physicians who have been thoroughly trained on the operation of the CoolWave Control Unit and the Cooled ThermoTherapy Procedure should deliver the treatment.

The Cooled ThermoTherapy Procedure must not be initiated without assurance that the microwave catheter is properly positioned in the patient. **The correct positioning of the microwave catheter must always be checked by ultrasound imaging prior to commencing treatment. Improper placement or orientation of the microwave catheter may lead to procedure failures or heating damage of non-target tissues such as the bladder neck, external sphincter, or penile urethra.**

All components of the CoolWave Control Unit must be used in a manner consistent with the instructions set forth in their respective instructions for use insert and the CoolWave Control Unit User Manual (this document). Failure to do so may result in insufficient treatment or increased risk of injury or infection to the patient.

Note: Use of the CoolWave Control Unit results in the deposition of microwave energy in the patient's prostate and in adjacent regions of the body. Some animal studies in the literature suggest that there may be as yet unknown health effects from exposure to microwave radiation, including an increased incidence of tumors. Although it is not possible to extrapolate these studies to humans, they suggest that unnecessary microwave radiation exposure should be avoided.

At least 20 cm of ventilation clearance must be provided around the base of the CoolWave® Control Unit.

Note: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the Federal Communication Commission (FCC) Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference, in which case the user will be required to correct the interference at his own expense.

The Urologix® CoolWave Control Unit emits a small amount of electromagnetic energy during a procedure. Urologix recommends that all electronic medical devices be kept at a minimum distance of 1.0 meter from the CoolWave Control Unit when performing a treatment. However, a 1-meter separation of electronic medical equipment from the CoolWave Control Unit does not guarantee that operation of other devices will not be impacted. The effect of this electromagnetic energy on all equipment cannot be predicted due to age and quality of maintenance. The performance of each piece of equipment operated near the CoolWave Control Unit, during a procedure, must be evaluated for degradation. For more detailed EMC requirements, refer to *Section 5.6 Electromagnetic Compatibility* (EMC) Tables in the Appendix.

Since microwave energy can travel through walls, ceilings, and floors to affect other devices, it is important to understand that the 1-meter safety distance applies not only to the treatment room, but also to all adjacent rooms in the building, including the rooms above and below the treatment room. Do not operate the CoolWave Control Unit near equipment that emits electromagnetic energy, unless the effect on the CoolWave Control Unit has been evaluated and no degradation of performance was found. The national standard ANSI/IEEE C95.1 - 1999 Edition (Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields) recommends a maximum stray field exposure level for whole body exposure of 3 mW/cm^2, as averaged for any 6 minute period. The maximum radiated field, at full power, from the CoolWave Control Unit patient cable and microwave catheter, at 5 centimeters, is 2.1 mW/cm^2. Urologix recommends that the operator maintain a minimum distance of 5 centimeters from the patient cable and exposed portions of the microwave catheter during the procedure.

Operate the CoolWave Control Unit and connected devices only when connected to a fully tested, hospital grade power outlet with adequate grounding.

The CoolWave Control Unit must be plugged into the appropriate voltage outlet.

The electrical equipment inside the CoolWave Control Unit uses voltages capable of causing serious injury or death from electric shock. To avoid this hazard, never open the housing of the CoolWave Control Unit.

1.5 Introduction to the CoolWave® Control Unit

The CoolWave Control Unit treats Benign Prostatic Hyperplasia (BPH) by applying microwave power to the prostate. This microwave power, when applied to the prostate, heats the diseased tissue via a microwave catheter. This microwave catheter also minimizes patient discomfort and risk to the urethra by circulating cooling fluid. In addition, rectal wall damage is prevented by continuously monitoring rectal wall temperature readings throughout the treatment. If during a treatment, urethra or rectal temperatures exceed protocol (treatment) parameters, the system will adjust microwave power to protect the urethra or rectal wall from overheating.

1.6 Targis® System: CoolWave® Control Unit equipment overview

The Targis System is comprised of a CoolWave control unit model 5000 series, a Procedure Kit (comprised of a microwave catheter, a rectal unit, and a coolant bag), and accessories. For this user manual, the representative microwave catheter is the CTC Advance® Microwave Catheter.

1.6.1 CoolWave Control Unit

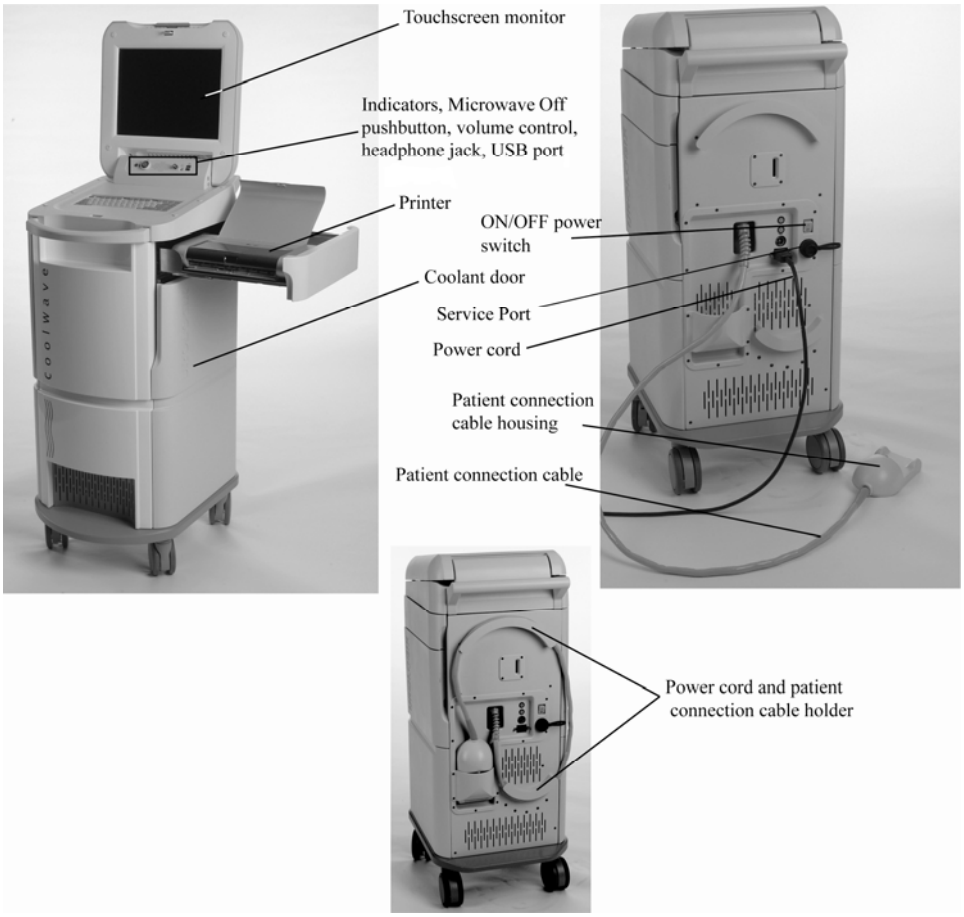


Figure 1-1. CoolWave Control Unit

The CoolWave® Control Unit (Figure 1-1) supplies microwave energy and coolant to the microwave catheter and collects temperature data from the microwave catheter and the rectal unit. The CoolWave Control Unit also provides a way of entering patient data, controlling treatment parameters (e.g., ramp rate, coolant temperature, and treatment time), and monitoring rectal and urethra temperatures. The CoolWave Control Unit includes these features:

- Patient connection cable and patient connection cable housing
- Touchscreen monitor
- Keyboard
- Printer
- ON/OFF power switch
- Lockable wheels
- Coolant system
- Main power indicator and microwave power indicator
- Microwave Off pushbutton
- Other: Volume control, headphone jack, USB ports

Note: The service port is reserved for use by Urologix® service personnel only.

Patient Connection Cable and Patient Connection Cable Housing

Data from the microwave catheter and the rectal unit enters the CoolWave Control Unit via the patient connection cable and patient connection cable housing (Figure 1-2).

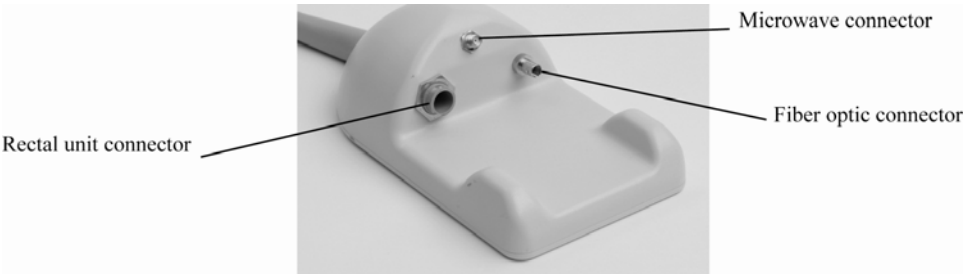


Figure 1-2. Patient Connection Cable Housing

The patient connection cable housing contains connectors for the rectal unit, fiber optic connector, and microwave antenna connector. When not in use, place the patient connection cable and housing in the cable holder located on the back of the CoolWave Control Unit.

Touchscreen monitor

View a treatment using the touchscreen monitor (Figure 1-3) and, when necessary, adjust treatment parameters. The monitor can be tilted for improved viewing. To open the monitor, operate the latch and lift.

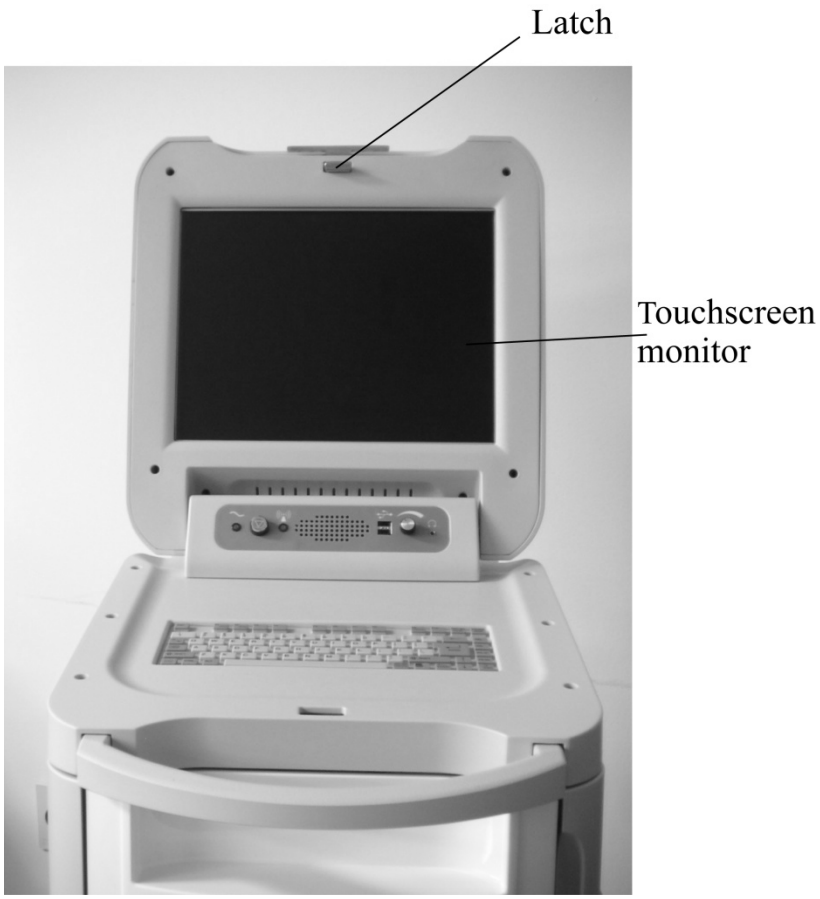


Figure 1-3. Touchscreen monitor

Keyboard

Enter patient data using the keyboard (Figure 1-4). The keys are sealed to prevent damage from spillage onto the keyboard. To access the keyboard, lift the touchscreen monitor into an upright position.

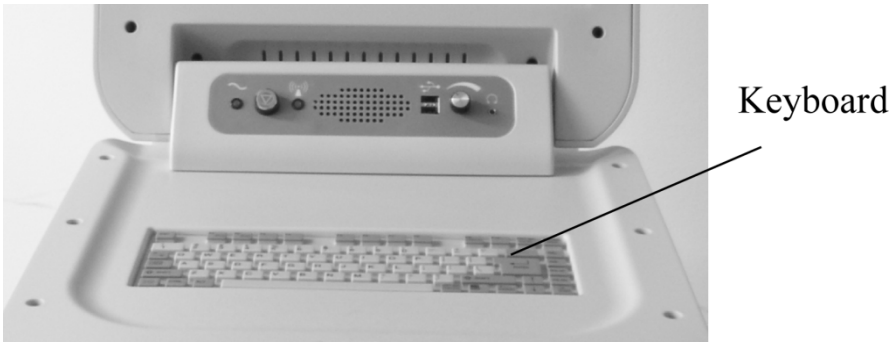


Figure 1-4. Keyboard

Printer

Print data from any treatment using the Canon® color inkjet printer (Figure 1-5). The printer drawer pulls out and holds the printer.

Caution: The CoolWave Control Unit can tip over if you press down on the open printer drawer with too much weight. Do not press down on the open drawer with more than 20 kg (44 lbs).

Figure 1-5. Printer

ON/OFF power switch

Instruction Manual: Read the CoolWave Control Unit User Manual (this document) before turning ON and operating the system.

Turn the CoolWave Control Unit ON or OFF with this power switch (Figure 1-6) located on the back of the CoolWave Control Unit. When not in use, place the power cord in the cable holder located on the back of the CoolWave Control Unit.

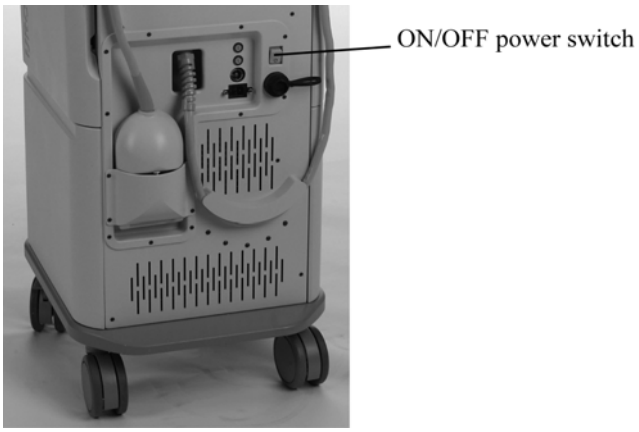


Figure 1-6. ON/OFF power switch

Lockable wheels

Keep the CoolWave® Control Unit from moving by locking the front wheels (Figure 1-7).

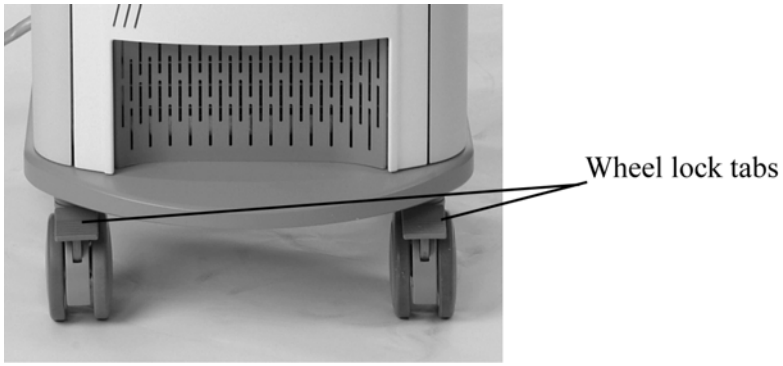


Figure 1-7. Wheel lock tabs

To lock the wheels, use your foot to press down on the wheel lock tabs. To unlock the wheels, press on the back part of the wheel lock tabs.

Coolant System

The coolant system consists of a chill plate, temperature and pressure sensors, a peristaltic pump mechanism, and a coolant bag (Figure 1-8).

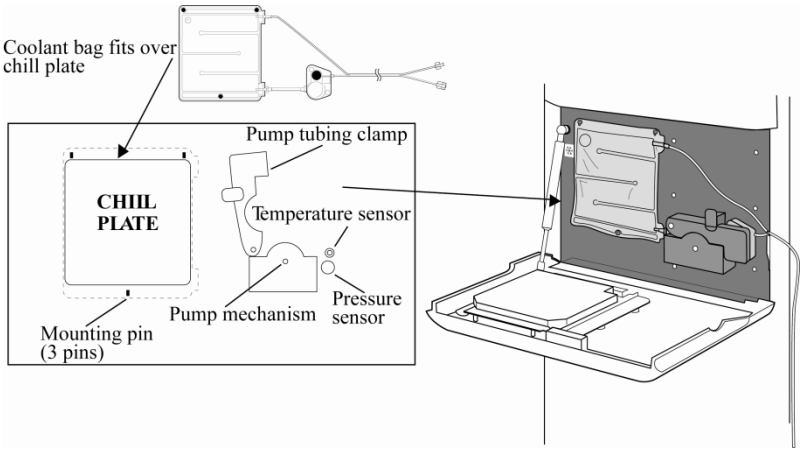


Figure 1-8. Coolant system features

Chill plate: The chill plate, located behind the coolant door (Figure 1-8), is equipped with mounting pins to hold the coolant bag securely against the chill plate surface.

Temperature and pressure sensors: These sensors, located on the CoolWave Control Unit, monitor the coolant temperature and the coolant pressure (Figure 1-8).

Peristaltic pump mechanism: The peristaltic pump mechanism (Figure 1-8) circulates the coolant.

Coolant bag: The coolant bag (Figure 1-8) serves as the reservoir for the coolant.

Main power indicator and microwave power indicator

The main power indicator (Figure 1-9), located under the touchscreen monitor, is a green LED that illuminates when the CoolWave® Control Unit is ON. The microwave power indicator (Figure 1-9), also located under the monitor, is an amber LED that illuminates when the CoolWave Control Unit delivers microwave power to the prostate.

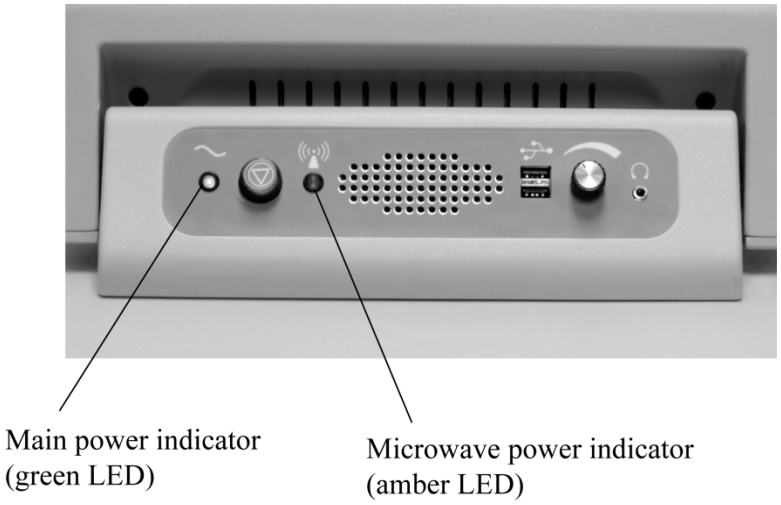


Figure 1-9. Power indicators

Microwave Off pushbutton

If there is an emergency, press the red **Microwave Off** pushbutton (Figure 1-10), located under the touchscreen monitor and right of the green LED, to immediately turn the microwave power OFF.

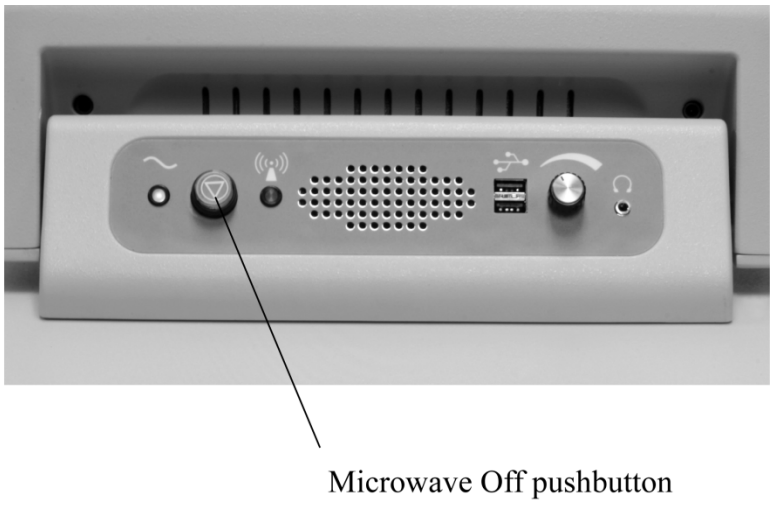


Figure 1-10. Microwave Off pushbutton

Other: Volume control, headphone jack, USB ports

The CoolWave® Control Unit includes a volume control, a headphone jack, and two USB (Universal Serial Bus) ports (Figure 1-11), all located under the touchscreen monitor. Either of the USB ports can accommodate a single USB flash drive.

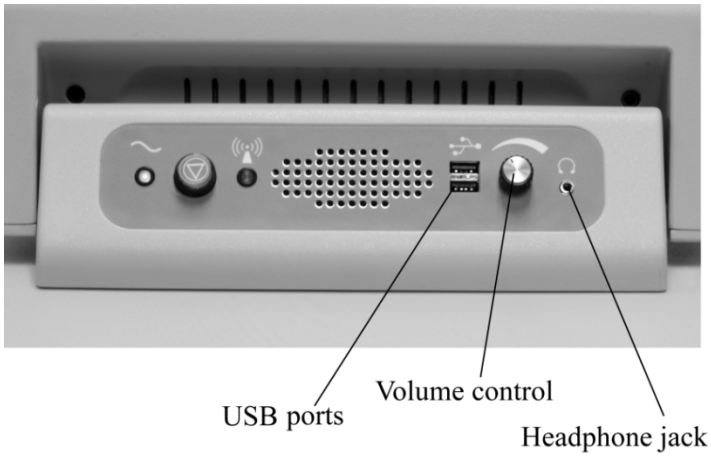


Figure 1-11. Volume Control, Headphone jack, USB Ports

1.6.2 Microwave Catheter

The single-use microwave catheter includes a fiber optic temperature sensor to measure urethra temperature, a microwave antenna and cable, cooling channels and connectors, a urine drainage port that connects to a standard urine drainage bag, and a location balloon to position the catheter at the bladder neck (Figure 1-12). The microwave antenna and temperature sensor are connected to the CoolWave Control Unit via the patient connection cable housing and patient connection cable. To ensure that the microwave catheter is positioned properly within the urethra, the location balloon is inflated to hold the catheter in place during treatment.

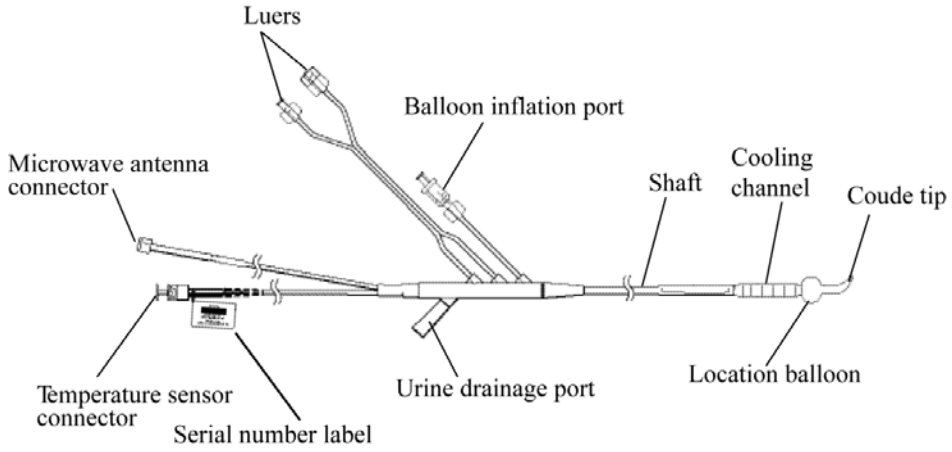


Figure 1-12. Microwave catheter

The microwave catheter is used for:

- Delivering microwave energy to the targeted prostatic tissue.
- Monitoring the urethra temperature.
- Cooling the urethra during treatment.
- Draining urine during treatment.

1.6.3 Rectal Thermosensing Unit (RTU)

The CoolWave Control Unit requires the use of either the single-use standard RTU or the RTU Plus with reusable handle and single-use balloon. The standard RTU and RTU Plus (Figure 1-13 and Figure 1-14) both consist of an inflatable balloon with 5 temperature sensors. These sensors monitor rectal temperature along the anterior rectal wall and send this information to the CoolWave Control Unit during a treatment. After inserting one of the rectal units into the rectum, inflating the rectal balloon with air holds the thermosensors in place against the anterior rectal wall nearest the prostate.

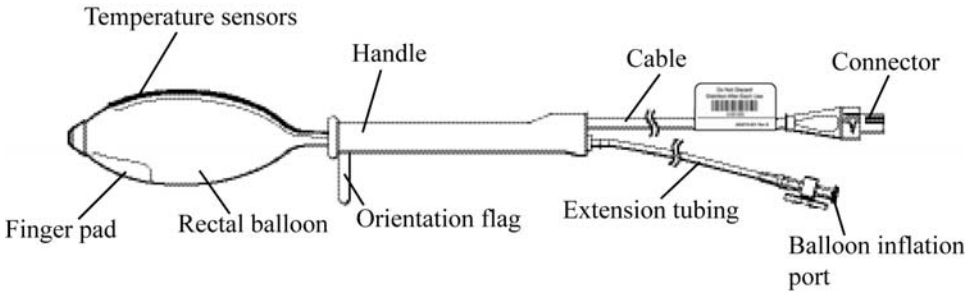


Figure 1-13. Single-use standard RTU

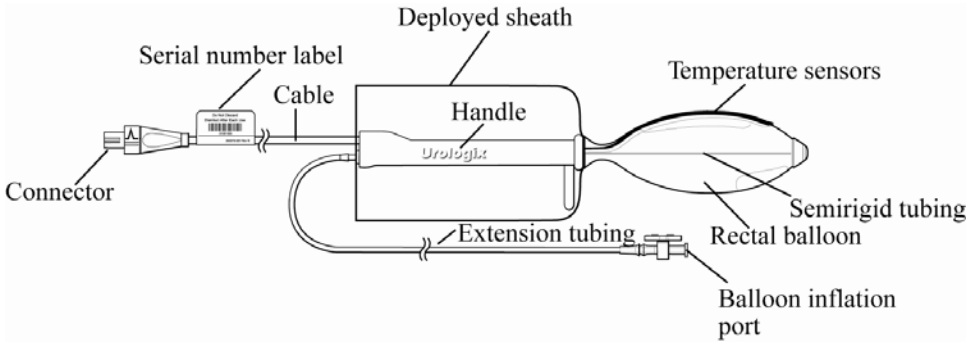


Figure 1-14. Assembled RTU Plus (with the reusable handle and single use balloon)

1.6.4 Coolant Bag

The single-use coolant bag includes a coolant bag, inlet and outlet tubing, connectors, and a sensor module (Figure 1-15). The sensor module allows the CoolWave® Control Unit to monitor coolant temperature and pressure in order to maintain coolant temperatures within acceptable limits and to ensure that the coolant circulates properly. The coolant bag also includes 2 small holes on the top and 1 hole on the bottom for mounting the bag on the chill plate and a hydrophobic vent to release air (but not coolant) from inside the bag.

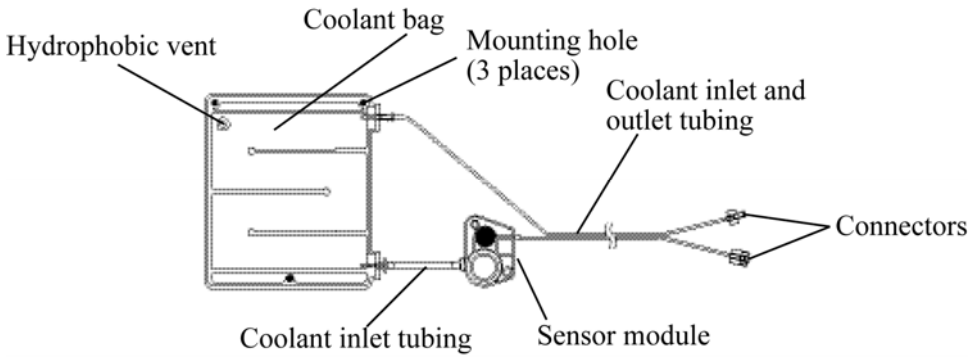


Figure 1-15. Coolant Bag

The function of the coolant bag is to provide a reservoir for the coolant that circulates through the microwave catheter during a treatment. The coolant circulates through the coolant bag via the peristaltic pump mechanism. The coolant inlet tubing runs across the pump mechanism, which pushes the coolant through the inlet tubing, the sensor module, the coolant bag, and the outlet tubing. Coolant continuously circulates through the microwave catheter, connected to the coolant outlet tubing, and returns to the coolant bag via the coolant inlet tubing. The coolant bag resides against the chill plate, which chills the circulating coolant.

1.7 Required equipment

The following equipment, **including an ultrasound system**, is needed to successfully treat patients with the CoolWave Control Unit.

1.7.1 Equipment provided by Urologix

Urologix provides the following equipment.

Quantity	Equipment/Material
1	CoolWave® Control Unit
1	CoolWave Control Unit User Manual (this document)
1	Kit containing either Targis®, Cooled ThermoCath®, or CTC Advance® Microwave Catheter • 1 microwave catheter • 1 Rectal thermal unit standard RTU or RTU Plus • 1 coolant bag
1	Patient Comfort Kit (2 knee cushions and a Microwave Catheter Holder)
1	Transport Kit, optional (trolley and electrical safety tester)

Table 1-2. Urologix provided equipment

1.7.2 Equipment Provided by the Clinic

The clinic typically provides the following equipment.

Quantity	Equipment/Material
1	Foley catheter, 16-18 French
1	Straight catheter, 14-16 French
1	Urine drainage bag
As needed	Sterile gloves
As needed	Anesthetic lubricating jelly (Urojet or lidocaine jelly)
50 cc	Local bladder anesthetic of choice (e.g., 50 cc of 1% or 2% lidocaine without epinephrine)
As needed	Water soluble lubricating gel (e.g., K-Y® Jelly)
1	60 cc luer-lock syringe
1	60 cc catheter-tip syringe (i.e., Toomey™ syringe)
2	10 cc luer-lock syringe
200 cc	Sterile water for coolant bag and catheter balloons
1	Ultrasound system
1	Catheter plug
As needed	Permanent marker or tape
As needed	Nonsterile gloves
1	Penile clamp
1	Specimen cup
1	Urinal or graduate
As needed	Ice or ice pack

Table 1-3. Clinic provided equipment

1.8 CoolWave® Control Unit Installation and Use Environment

1.8.1 Installation

Warning: DO NOT USE components that have evidence of a compromised package or damage.

Before unpacking the CoolWave Control Unit, inspect the shipping crate for signs of damage. Remove the CoolWave Control Unit from the shipping crate, and retain the shipping crate to return the CoolWave Control Unit for service, if needed. Then, prior to using the CoolWave Control Unit, visually inspect the following components for damage:

- CoolWave Control Unit for obvious damage
- Pump latch and coolant door to see that they are operating correctly
- Patient connection cable, patient connection cable housing, and connectors for kinks, cuts, dirt, contamination, or obvious damage
- Microwave catheter for kinks, cuts, or obvious damage
- Rectal unit for kinks, cuts, or obvious damage
- Coolant Bag for kinks, cuts, or obvious damage

Operate the CoolWave Control Unit and its connected devices only in clinical environments where it can be connected to a fully tested, hospital-grade power outlet with adequate grounding.

Power requirements

CoolWave Control Unit, Model 5000E (Europe):	220/240 V [+/- 10%] (4.25 A) Single phase 50 or 60 Hz
CoolWave Control Unit, Model 5000A (US):	110/120 V [+/- 10%] (8.5 A) Single phase 50 or 60 Hz

If required, an equal potential ground cable should be connected to the CoolWave Control Unit (Figure 1-16) and the appropriate ground.

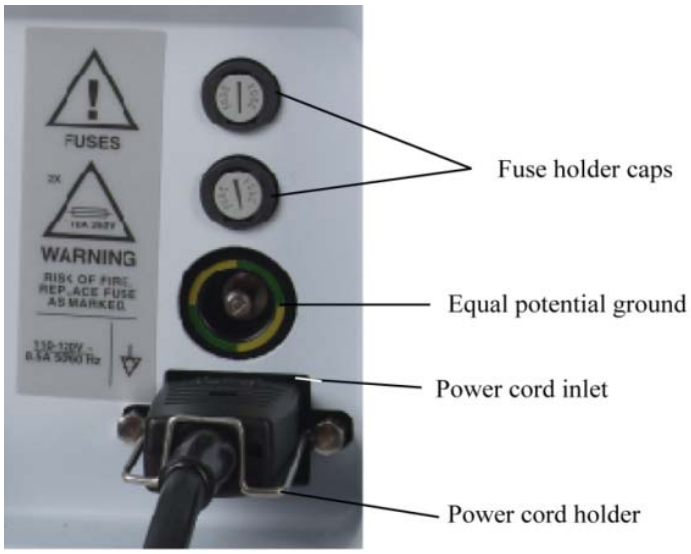


Figure 1-16. CoolWave Control Unit Rear

CoolWave® Control Unit Power Cords

Urologix provides the following power cords for use with the CoolWave Control Unit.

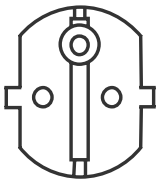
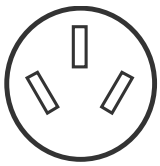
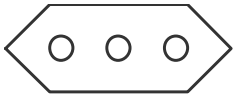
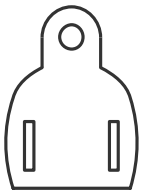
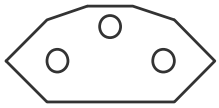
End View	Power Cord Catalog Number
	Catalog Number: AC1011 France Austria Germany Norway Belgium Sweden Netherlands Finland
	Catalog Number: AC1012 Australia New Zealand
	Catalog Number: AC1013 United Kingdom Ireland
	Catalog Number: AC1014 Denmark
	Catalog Number: AC1015 Italy
	Catalog Number: AC1017 Canada United States Mexico
	Catalog Number: AC1018 Switzerland

Table 1-4. CoolWave Control Unit Power Cords

Equipment connections

The CoolWave Control Unit must not be connected to any device other than the microwave catheter, rectal unit, or coolant bag. In addition, the microwave catheter, rectal unit, and coolant bag must not be connected to any other device or outlet.

Equipment testing

Turn the CoolWave® Control Unit ON, and verify that the Login screen display appears. Do not use the CoolWave Control Unit if there are any irregular sounds or vibrations present.

Prior to beginning a Cooled ThermoTherapy™ procedure, verify that all components of the Procedure Kit (microwave catheter, RTU, and coolant bag) have arrived in a sealed condition.

1.8.2 Use Environment

Cautions:

- Do not stack any objects on top of CoolWave Control Unit, microwave catheter, RTU, or coolant bag.
- Do not place the CoolWave Control Unit near any electronic device or other equipment emitting electromagnetic waves. The interference may compromise the operation of the equipment.
- Provide ventilation space of at least 20-cm clearance around the base of the CoolWave Control Unit for operation.
- Do not turn ON the CoolWave Control Unit with the touchscreen monitor lid closed. The touchscreen will turn OFF, and the lid may become warm to the touch.
- Operate the CoolWave Control Unit on a level surface.
- Operate the CoolWave Control Unit under these operating conditions:
  An ambient temperature range of +10°C to +30°C,
  A relative humidity range of 30% to 75%,
  An atmospheric pressure range of 700 hPa to 1,060 hPa

1.9 Safety instructions

Warning: Do not open the housing of the CoolWave Control Unit. Doing so risks receiving an electric shock. Refer all CoolWave Control Unit servicing to qualified Urologix® personnel.

Warning: This equipment is not intended for use in areas where there is a danger of explosion. Do not use the CoolWave Control Unit in the presence of flammable substances.

Caution: The CoolWave Control Unit must be operated by trained and authorized personnel. You should read and understand the instructions in this manual before operating the system.

This manual does not claim to address all of the safety concerns associated with the use of this equipment. You must establish appropriate safety and health practices prior to use.

Perform the following CoolWave Control Unit safety checks at least once every 12 months:

- Cables and connectors for damage
- Equipment for physical damage
- Safety labels are readable

Maintain a written record of these safety checks, and service any equipment that does not meet these standards.

2 Treatment Session Setup

2.1 General safety precautions

The CoolWave® Control Unit is a medical device equipped with the ability to emit microwave radiation. Therefore, observe the following general safety precautions:

- The CoolWave Control Unit must only be installed and serviced by qualified service personnel.
- The CoolWave Control Unit may not be used for any purpose other than those for which it is designed and approved, and then only in accordance with this manual.
- The CoolWave Control Unit may be used only by authorized and properly trained personnel and the treating physician must be present throughout the duration of the Cooled ThermoTherapy™ procedure. The CoolWave Control Unit display must be monitored and controlled during the course of a treatment session to make sure that the urethral and rectal temperatures are within prescribed treatment parameters.
- The CoolWave Control Unit must never be left unattended when the machine is switched ON.

The CoolWave Control Unit is exclusively for use by physicians who have been trained.

The treating physician should be present at all times during treatment.

2.2 Treatment session setup overview

The treatment session requires several preparation steps. Some of these steps may be done concurrently.

1. Preparing the patient for treatment.
2. Positioning and preparing the CoolWave Control Unit.
3. Installing the coolant bag.
4. Inserting the microwave catheter.
5. Inserting the single-use standard RTU, or inserting the RTU Plus with reusable handle and single-use balloon.
6. Connecting the microwave catheter and RTU to the CoolWave Control Unit.

2.3 Preparing the Patient for Treatment

1. Ensure the patient has received adequate information about the treatment and post-treatment expectations and has provided informed consent.

2. Perform an enema 1 to 2 hours before treatment or per physician instructions. **An enema is mandatory.**
3. Administer pre-procedure medications such as local anesthetics, antibiotics, non-steroidal anti-inflammatory agents, analgesics, or anti-anxiety medications (generally given 1 hour prior to the start of microwave power delivery). It is important that the patient not be over sedated. This may compromise his ability to communicate pain.

Note: Medications, such as anti-inflammatory agents, may be given to the patient at the discretion of the physician based on the patient's physical and mental well-being.

2.4 Positioning and preparing the CoolWave® Control Unit

1. Position the CoolWave Control Unit on a level surface and close enough to the patient so that the patient connection cable connects easily to the microwave catheter and the RTU.

2. Lock the front wheels of the CoolWave Control Unit to prevent it from accidentally moving. To lock the wheels, use your foot to press down on the wheel lock tabs. To unlock the wheels, press on the back part of the wheel lock tabs.

3. Plug the CoolWave Control Unit electrical cord to a wall outlet. The connection requires a fully tested, hospital-grade power outlet with adequate grounding, and the power supply must meet the following specifications:

Power requirements	
Control Unit, Model 5000E (Europe):	220/240 V [+/- 10%] (4.25 A) Single phase 50 or 60 Hz
Control Unit, Model 5000A (US):	110/120 V [+/- 10%] (8.5 A) Single phase 50 or 60 Hz

Warning: Do not move the CoolWave Control Unit while the electrical cord is connected to a power source.

4. Turn ON the CoolWave Control Unit and login to the system. Refer to *Section 3.2, CoolWave® Control Unit setup***,** for further information.

Note: Turn ON the CoolWave Control Unit at least 5 minutes before treatment begins to allow the system to warm up.

5. Enter patient and clinical information on the Patient Information screen. Refer to *Section 3.3.1, Patient Information screen*, for further information.

Note: For first-time users, it may be helpful to read *Section 3.1, System Navigation and Screen Overview*, prior to entering patient and clinical information on the Patient Information screen.

2.5 Installing the Coolant Bag

Instruction Manual: Read the CoolWave Control Unit User Manual (this document) before installing the Coolant Bag.

1. Open the package containing the coolant bag, and remove the coolant bag.

2. Fill the coolant bag with 100 cc (± 5 cc) of sterile water by injecting the water into the female luer fitting of the coolant bag with a syringe (Figure 2-1).

Cautions:

- Use only sterile water in the coolant bag. Do not fill the coolant bag with saline solution. Saline solution has electrical properties that can interfere with microwave energy from the microwave catheter during treatment.
- Do not allow the coolant bag connectors to fall on the floor during installation.

Note: To prevent water from leaking out of the coolant bag once it has been filled, temporarily connect the coolant bag connectors together.

Figure 2-1. Filling the coolant bag

3. Open the coolant door on the right side of the CoolWave® Control Unit by pulling the top of the door forward. Position the coolant bag over the chill plate by aligning the top two mounting holes of the coolant bag with the top two mounting pins on the chill plate. Gently position the coolant bag onto the pins (Figure 2-2).

Figure 2-2. Positioning the Coolant Bag onto the Top Mounting Pins

4. Position the bottom mounting hole of the coolant bag over the lower mounting pin below the chill plate to complete the process of installing the coolant bag (Figure 2-3).

Figure 2-3. Positioning the Coolant Bag onto the Lower Mounting Pin

5. Route the coolant inlet tubing through the pump mechanism by pulling out the locking lever, located on the upper pump tubing clamp, and lifting the tubing clamp up (Figure 2-4).

6. Lay the coolant inlet tubing across the center of the pump mechanism. When the coolant bag is mounted correctly on the chill plate, the inlet tubing and sensor module are aligned with the pump mechanism (Figure 2-4).

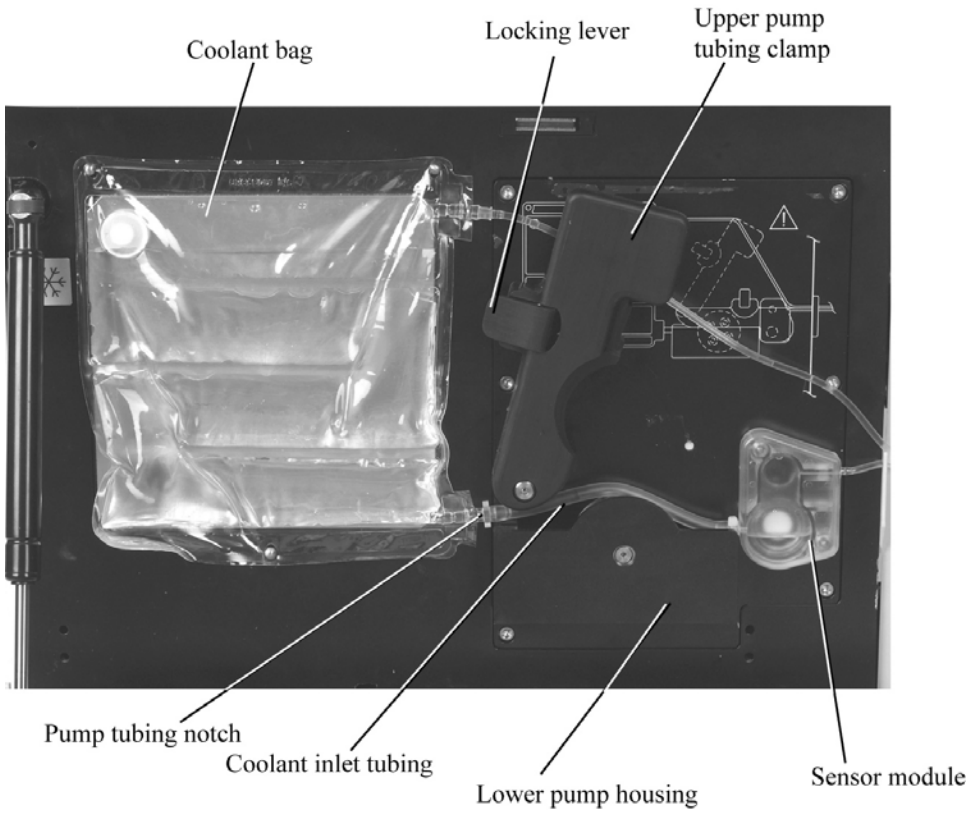


Figure 2-4. Coolant System with Pump Mechanism Open

7. Place the coolant inlet tubing under the upper pump tubing clamp and across the rotor of the pump mechanism (Figure 2-4).

Note: Ensure that the coolant inlet tubing is not twisted.

8. Align the sensor module with the locating pins to the right of the pump mechanism (Figure 2-5).

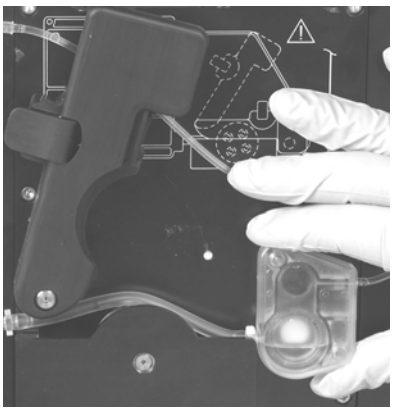


Figure 2-5. Positioning the Sensor Module

9. Ensure the coolant inlet tubing is properly seated in the notch of the lower pump housing. Then, firmly push down on the upper pump tubing clamp until it snaps into position (Figure 2-6).

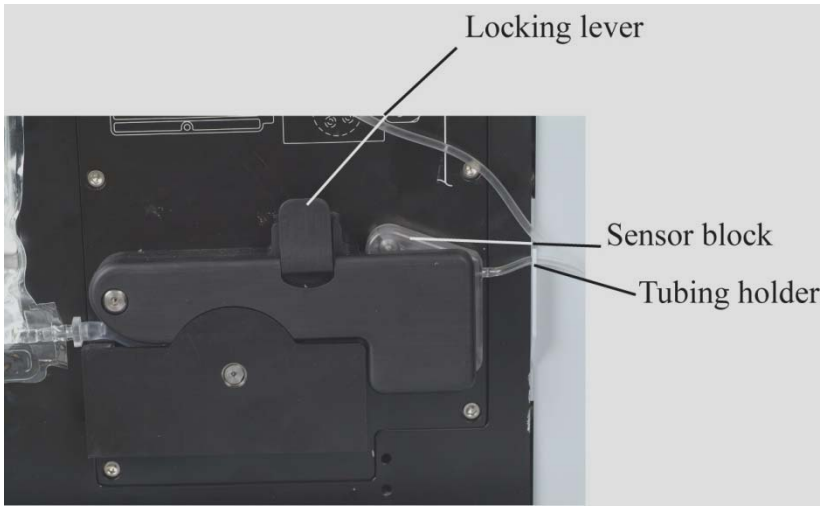


Figure 2-6. Coolant System with Pump Closed

10. Insert the coolant inlet and outlet tubing into the tubing holder. This will prevent the tubing from being pinched by the coolant door.
11. Close the coolant door completely.

Note: The coolant delivered to the microwave catheter may not be at the desired temperature if the coolant door is not completely closed. In addition, a closed coolant door prevents damage to the coolant bag.

2.6 Inserting the microwave catheter

1. Drain the patient's bladder using only water-soluble lubricant in the process.
2. Instill an anesthetic mixture of choice into the bladder.
3. Insert a water-based anesthetic lubricant mixture of choice into the urethra, and clamp the penis to contain the lubricant mixture within the urethra for 20-30 minutes.

Warning: Do not overinflate the microwave catheter balloon. Overinflation may result in balloon malfunction and possible improper positioning of the microwave antenna. Underinflation can cause the antenna to be misplaced in the prostate, affecting the external sphincter.

Warning: Selection and use of the appropriate catheter model is required to assure patient safety. Verify that the correct catheter has been inserted in the patient using the catheter identifiers provided in Table 2-1. Microwave Catheter Identification.

Microwave Catheter	Prostatic Urethral Length	Catheter Color Scheme	Serial Number Tag Color	Serial Number Prefix
CTC Advance® - Short	2.5 to 3.5 cm	Blue Handle Black Accents	Black	TH
CTC Advance® or Cooled ThermoCath® - Standard	3.0 to 5.0 cm	Blue* Handle White Accents	White	TC
CTC Advance® or Cooled ThermoCath® - Long	≥ 4.5 cm	Blue* Handle Grey Accents	Grey	TF
Targis® - Short	2.5 to 3.5 cm	White Catheter Green Handle	Green	AB
Targis® - Standard	3.0 to 5.0 cm	White Catheter White Handle	Blue	AB

Table 2-1. Microwave Catheter Identification

*NOTE: A dark blue handle is Cooled ThermoCath®, the light blue is the CTC Advance®.

Note: The serial number label is attached to the cable of the microwave catheter near the connection to the patient cable.

Caution: The microwave antenna on the distal end of the microwave catheter may break if you bend it. Do not grab the microwave catheter or squeeze it in the area of the antenna or the shaft. The optical fiber located in the flexible shaft may be broken if it is clamped.

4. Open the package containing the microwave catheter (Figure 2-7). Test the location balloon by filling it with 10 cc of sterile water and examining it for leaks.

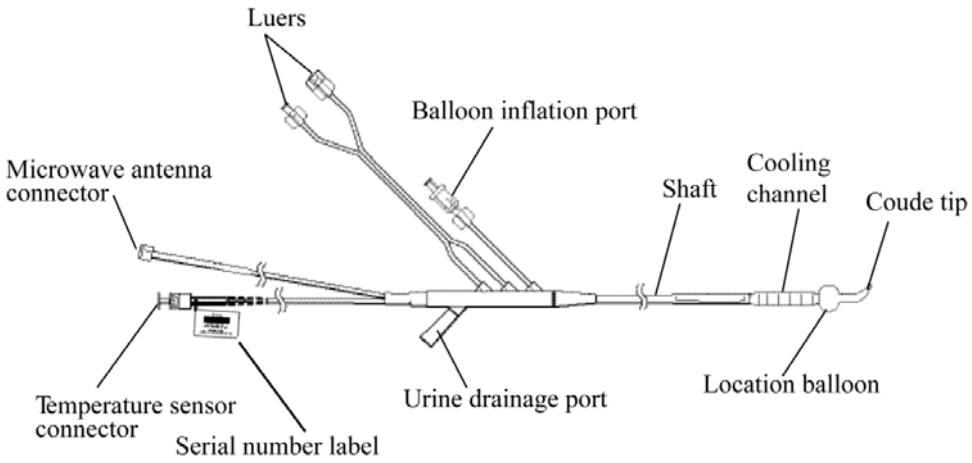


Figure 2-7. CTC Advance® Microwave Catheter

Note: For this user manual, the representative microwave catheter is the CTC Advance® Microwave Catheter.

5. Lubricate the microwave catheter with a water-based lubricant or local anesthetic.
6. Insert the microwave catheter into the patient's urethra until the location balloon is completely in the bladder. Align the microwave catheter so that the urine drainage port is pointed toward the patient's posterior and the coolant tubing is in an anterior orientation.

Warning: Avoid excessive force when pulling back on the microwave catheter to seat the balloon at the bladder neck. Excessive force could injure the patient or damage the catheter.

7. Inflate the location balloon with 10 cc of sterile water. Pull back on the microwave catheter until mild resistance is felt.

8. Flush the urine drainage lumen with 4-5 cc of sterile water. Insert a catheter plug (to retain bladder anesthetic, if used), or attach a urine drainage bag.

Note: Failure to flush the urine drainage lumen may cause system calibration errors.

9. Position the microwave catheter properly by pulling on it until the balloon is seated in the bladder neck, locating the microwave antenna within the preprostatic urethra (Figure 2-8). **Verify microwave catheter position with the ultrasound probe.**

Warning: Proper position of the location balloon is essential to patient safety.

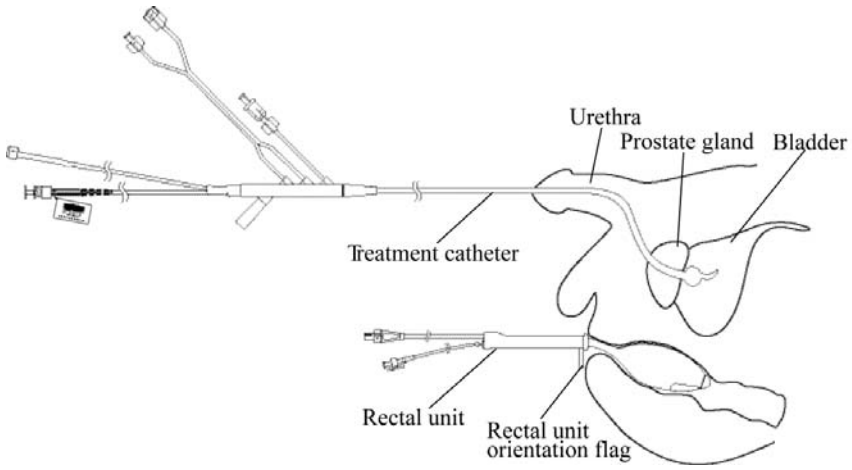


Figure 2-8. Inserted Microwave Catheter and Standard RTU

10. If the microwave catheter position is not acceptable, it may have to be rotated or reinserted. Push the catheter through the urethra until the tip and the location balloon is completely in the bladder. Rotate the microwave catheter, and then pull back until you feel mild resistance (Figure 2-8). Verify the microwave catheter position with ultrasound prior to proceeding with rectal unit insertion.

2.7 Inserting the Single-Use Standard RTU

1. Verify the patient has received an enema.
2. Open the package, and remove the rectal unit (Figure 2-9).

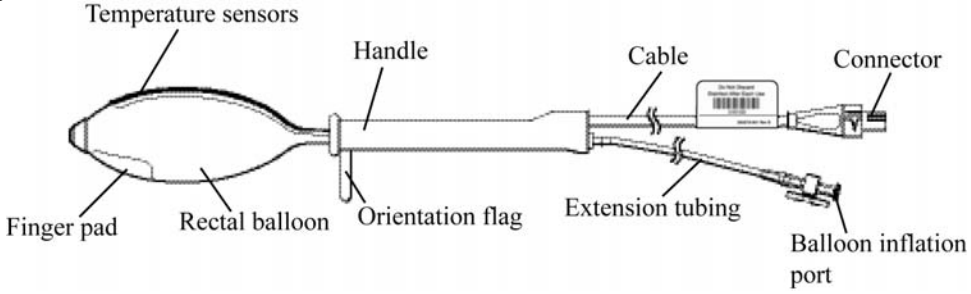


Figure 2-9. Standard RTU

3. Deflate the rectal balloon completely by attaching a 60 cc syringe to the inflation port and withdrawing air. The balloon should be deflated with the temperature sensors midline.

4. Lubricate the rectal balloon with a water-based lubricant (e.g. K-Y® Jelly), and insert the balloon into the rectum with the index finger. Inserting the balloon can be done with the patient on his side or supine with knees bent. The temperature sensors must be oriented toward the prostate. The orientation flag must be pointing toward the patient's posterior.

Warning: The rectal unit must be positioned properly to ensure correct temperature sensing.

5. Inflate the rectal balloon by injecting 120 cc of air into the inflation port, located on the proximal end of the rectal unit. Adjust air volume for patient comfort to no less than 80 cc. Close the valve on the inflation port.
6. Re verify proper positioning of the rectal unit by observing that the orientation flag, located on the balloon, is facing away from the prostate and toward the patient's posterior.

Warning: A minimum of 80 cc of air in the standard RTU rectal balloon is required to maintain contact between the temperature sensors and the rectal wall.

Warning: This visual reference should be made every 5 to 10 minutes throughout the treatment to verify the proper position of the rectal unit. Failure to properly orient the rectal unit during treatment can result in patient injury (e.g. fistula or scrotal burn).

2.8 Inserting the RTU Plus Reusable Handle and Single-Use Balloon

1. Verify the patient has received an enema.
2. Open the package for the RTU Plus Reusable Handle, or obtain a disinfected RTU Plus Handle from a previous treatment (Figure 2-10). The RTU Plus Handle with the temperature sensors should not be used in more than 30 treatments.

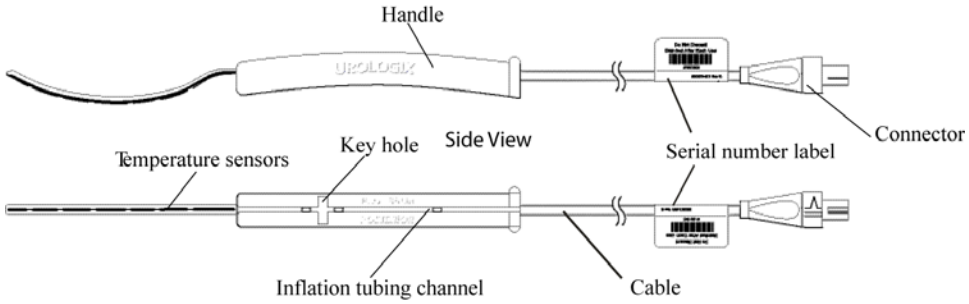


Figure 2-10. RTU Plus Reusable Handle

3. Open the package for a RTU Plus Disposable Balloon (Figure 2-11).

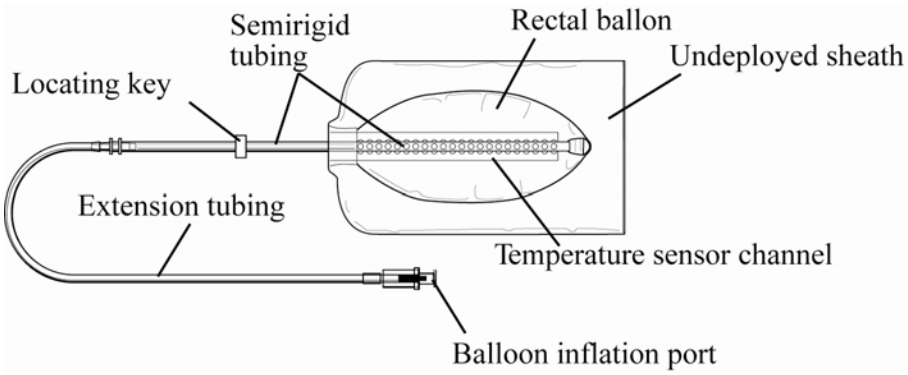


Figure 2-11. RTU Plus Disposable Balloon

4. Insert the temperature sensor strip into the sensor channel of the disposable balloon, as shown in Figure 2-12. Orient the sensors toward the outside of the balloon, and do not bend the temperature strip significantly. The temperature sensor strip should extend to the distal end of the channel, and the temperature sensor channel should be aligned with the top side of the handle.

Figure 2-12. Inserting the Temperature Sensor Strip

5. Seat the balloon inflation tubing in the inflation tubing channel located in the base of the rectal unit handle. The locating key should snap into place within the handle key hole; if not, reorient/reassemble the device. The proper positioning of the temperature sensor strip in the disposable balloon is assured by the locating key/handle interaction (Figure 2-13).

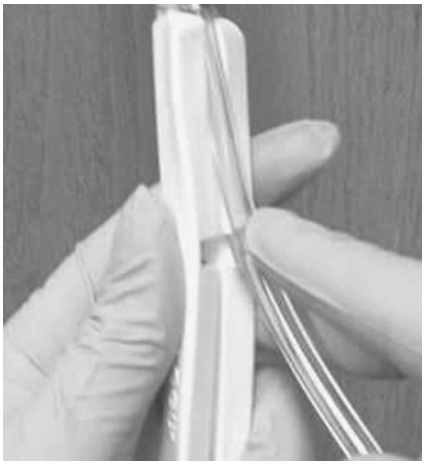


Figure 2-13. Proper Positioning of the Temperature Sensor Strip

6. Slide the protective sheath down from the balloon, and pull it over the handle as shown in Figure 2-14.

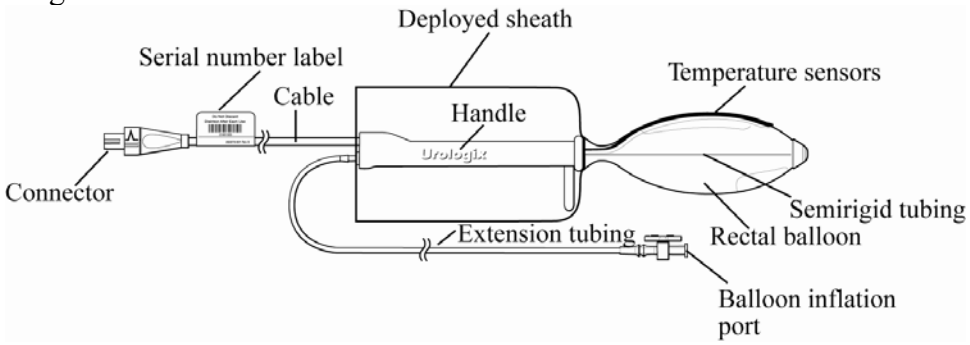


Figure 2-14. Assembled RTU Plus with Deployed Sheath

7. Attach a syringe to the inflation port, and inflate the balloon with approximately 90 cc of air to verify that no leaks are present. Remove all air to ensure that the balloon is completely deflated. Then, remove the syringe before proceeding to step 8.
8. Lubricate the balloon area with a water-based lubricant (e.g. K-Y Jelly).

Warning: The rectal unit must be positioned properly to ensure correct temperature sensing.

9. Insert the balloon slowly into the rectum using the semirigid tubing to guide placement. This can be done by initially grasping the sensor/support tubing in the middle of the balloon area and slowly introducing the balloon into the rectum. Then, move the guiding hand back to the handle. Slowly advance the balloon while grasping the handle until the entire balloon is inserted. Inserting the balloon can be done with the patient on his side or supine with knees bent.

   Note: The rectal temperature sensors must be oriented toward the prostate: The RTU Plus Reusable Handle is labeled anterior and posterior to help with placement.

10. Verify rectal unit orientation by confirming that the inflation tubing channel in the rectal unit handle (Figure 2-10) is facing towards the patient's posterior. Therefore, with the patient supine, the handle base would be against the treatment table surface with the Urologix® logo visible on both sides of the handle. This orientation ensures that the temperature sensors of the RTU Plus are pointed towards the patient's anterior rectal wall nearest the prostate.

Warning: This visual reference should be made every 5 to 10 minutes throughout the treatment to verify the proper position of the rectal unit. Failure to properly orient the rectal unit during treatment can result in patient injury (e.g. fistula or scrotal burn).

Warning: A minimum of 70 cc of air in the RTU Plus rectal balloon is required to maintain contact between the temperature sensors and the rectal wall.

11. Inflate the rectal balloon by injecting 90 cc of air into the inflation port, located on the proximal end of the rectal unit. Adjust the air volume for patient comfort to 70 cc. Remove the syringe.
12. The physician must confirm the proper positioning of the rectal unit prior to proceeding.

Note: When using an RTU Plus Reusable Handle, the Protocol screen will display the number of times the handle has been used and the number of remaining uses. The RTU Plus Reusable Handle should not be used in excess of 30 times.

2.9 Connecting the Microwave Catheter and Rectal Unit to the CoolWave® Control Unit

Warning: Excessive elevation of the patient torso may put additional pressure on the rectal unit, resulting in increased patient discomfort and higher rectal temperatures.

1. If the rectal unit was placed in the rectum while the patient was on his side, reposition the patient supine, with head and shoulders at no greater than a 20º angle. This position relieves pressure on the rectal unit and increases patient comfort.
2. Pull gently on the microwave catheter to reseat the location balloon at the bladder neck in case it moved during rectal unit insertion. If ultrasound was not used to verify microwave catheter position prior to rectal unit insertion, use ultrasound at this point to verify proper microwave catheter position.
3. Position the rectal unit cable underneath the microwave catheter holder. Secure the microwave catheter into the microwave catheter holder, with the cooling lines in the anterior position, once the microwave catheter position is acceptable. If desired, position the patient's legs on the knee cushions that come with the Patient Comfort Kit. Refer to *Section 5.4, Patient Comfort Kit*, to view the accessories in the kit.

4. Make a mark, with a permanent marker or tape, on the microwave catheter at the meatus. Use this mark as a visual reference to confirm proper microwave catheter position.

Warning: This visual reference should be checked every 5-10 minutes throughout the treatment to verify the proper position of the microwave catheter and of the rectal unit.

5. Secure the microwave catheter fiber optic and microwave connectors to the patient connection cable housing (Figure 2-15).

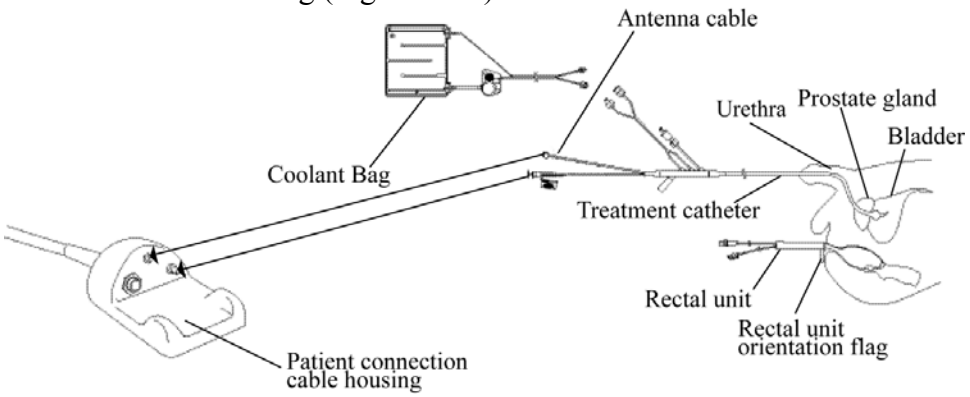


Figure 2-15. Connected Microwave Catheter and Rectal Unit

6. Connect the male luer fitting of the microwave catheter coolant tubing to the female luer fitting of the coolant bag tubing. Then, flush the female luer fitting of the microwave catheter coolant tubing with 4-5 cc of sterile water, and connect the microwave catheter to the coolant bag. This will preinflate the microwave catheter cooling channel.

Warning: Do not touch the antenna cable or the catheter handle while microwave power is ON. Touching the cable or the handle while microwave power is ON can cause burns. To prevent burns during treatment, isolate the antenna cable and the catheter handle away from the patient's legs.

7. To reduce the risk of burns, isolate the antenna cable (Figure 2-15) and the catheter handle away from the patient's legs:
   - Using the microwave catheter holder from the Patient Comfort Kit to secure the microwave catheter/antenna cable/handle location (Figure 2-16),
   - If the microwave catheter holder is not available, place the antenna cable and handle between the patient's legs—not over the legs—and use a towel to isolate the legs and keep them from moving.
   - Then, verify that the cable and handle are sufficiently isolated from the patient prior to beginning treatment

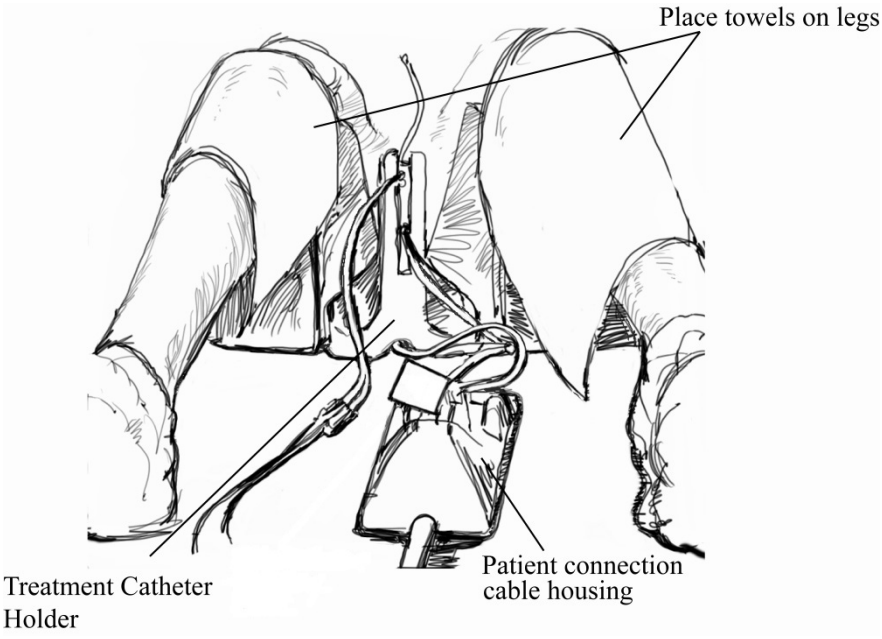


Figure 2-16. Isolate the Antenna Cable and Catheter Handle Using the Microwave Catheter Holder

8. Connect the rectal unit connector to the patient connection cable housing (Figure 2-17).

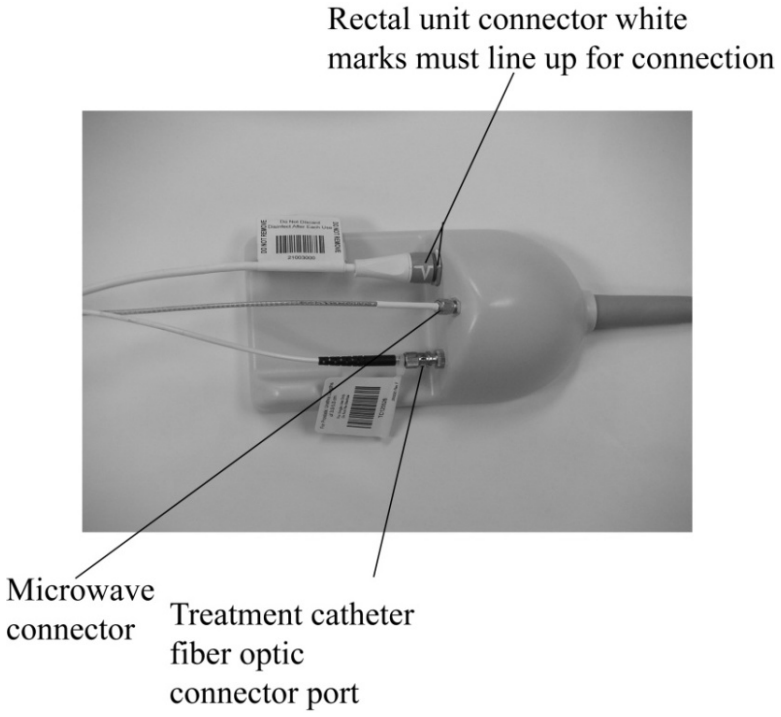

Rectal unit connector white marks must line up for connection
Microwave connector
Treatment catheter fiber optic connector port

Figure 2-17. Patient Connection Cable Housing

9. If not already completed, attach a urine drainage bag to the urine drainage port of the microwave catheter.

10. Proceed to *Section 3, Treatment Instructions*, for information on how to perform a Cooled ThermoTherapy™ Treatment.

3 Treatment Instructions

3.1 System Navigation and Screen Overview

This section provides the information needed to navigate the CoolWave® Control Unit as well as an overview of the screens, including demonstration mode. Please read this section prior to using the CoolWave Control Unit for the first time.

3.1.1 System Navigation

The CoolWave Control Unit includes a touchscreen monitor. This touchscreen monitor makes it easy to move around in the CoolWave Control Unit. Simply use your finger to gently press on the buttons on the screen. You will hear a "tick" sound when you press a button. You may also notice that a "pressed" button looks flat on the screen while a "nonpressed" button looks more 3-dimensional (Figure 3-1).

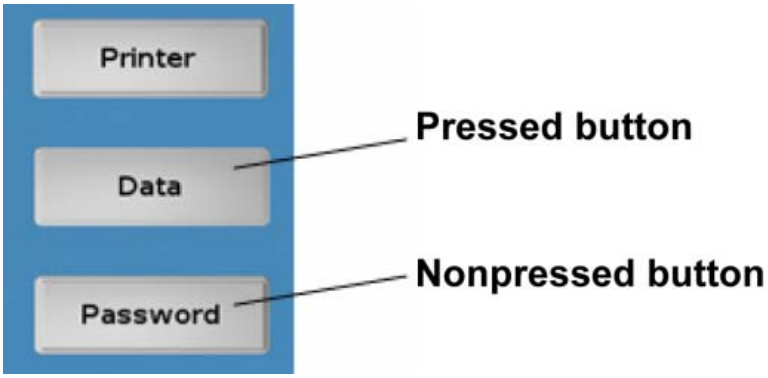


Figure 3-1. Pressed and Nonpressed Buttons

Some screens require entering information into a data field (Figure 3-2). Touch the screen in the desired data field, and when the cursor appears in that data field, use the keyboard to enter the requested information.

Note: You only need to touch the data field once with your finger to activate the operation of that field.

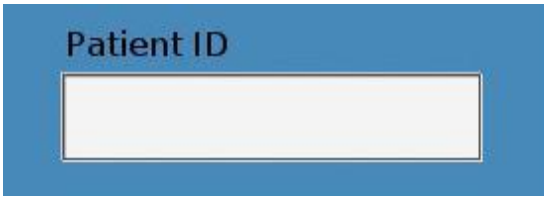
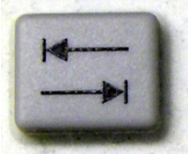


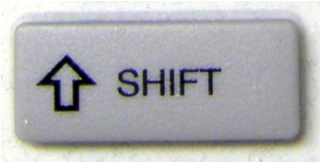
Figure 3-2. Data Field

When you are done entering information, touch the screen in the desired data field or use the TAB key (or the TAB and SHIFT keys) to move from one data field to the next data field.

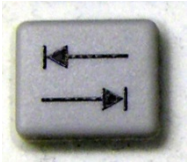


TAB KEY

Press the TAB key to move the cursor ahead to the next data field.



SHIFT KEY



TAB KEY

Press and hold the SHIFT key while pressing the TAB key to move the cursor back to the previous data field.

In addition, you will encounter dialog boxes as you use the CoolWave® Control Unit. A dialog box provides additional information or instruction (Figure 3-3). When a dialog box appears on the screen, read the information or follow the instructions before continuing with the Cooled ThermoTherapy™ Treatment.

Figure 3-3. Example of a CoolWave Control Unit Dialog Box

Demonstration mode

If you are training on the CoolWave Control Unit, you will be in demonstration mode. Demonstration mode simulates a Cooled ThermoTherapy Treatment and allows you to work with the CoolWave Control Unit as though you were performing a treatment on a patient. Follow the instructions in *Section 3, Treatment Instructions*, and look for additional information regarding demonstration mode under the heading **Demonstration mode**.

3.1.2 Screen Overview

The following information appears on all of the CoolWave® Control Unit screens, except for the Login screen: date, time, screen name, user name, and software version. Each screen, except for the Login screen, also contains access to the CoolWave Control Unit help feature, which contains the CoolWave Control Unit User Manual. In addition, on the treatment screens, you will find a Notes button. This button provides access to the notes feature where you can enter patient or treatment information (Figure 3-4).

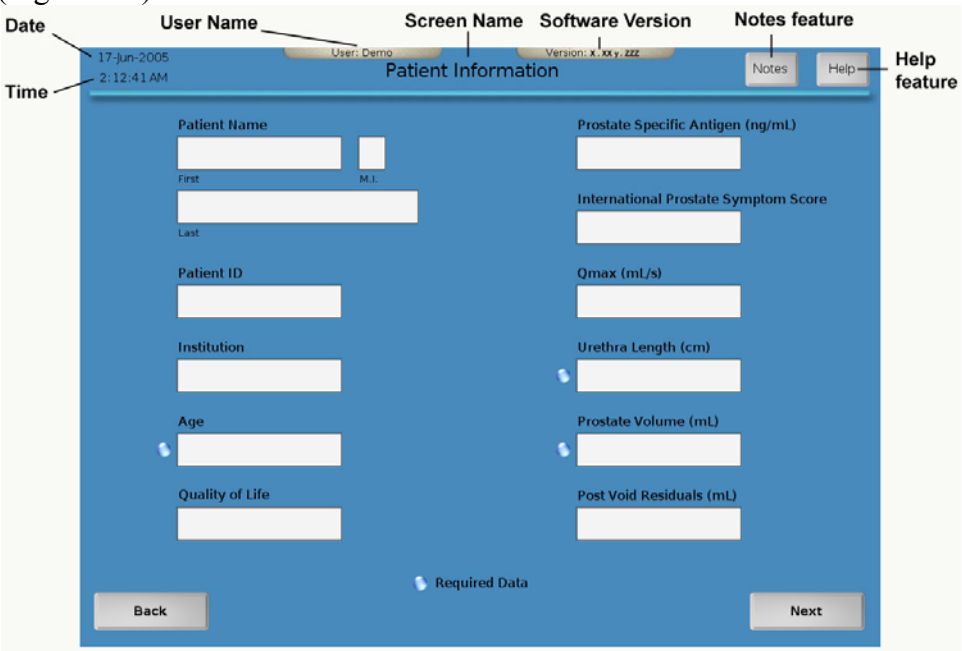


Figure 3-4. Screen Overview

Demonstration mode

A yellow bar at the top of the screen, with the text “Demonstration Mode,” signals that you are in demonstration mode.

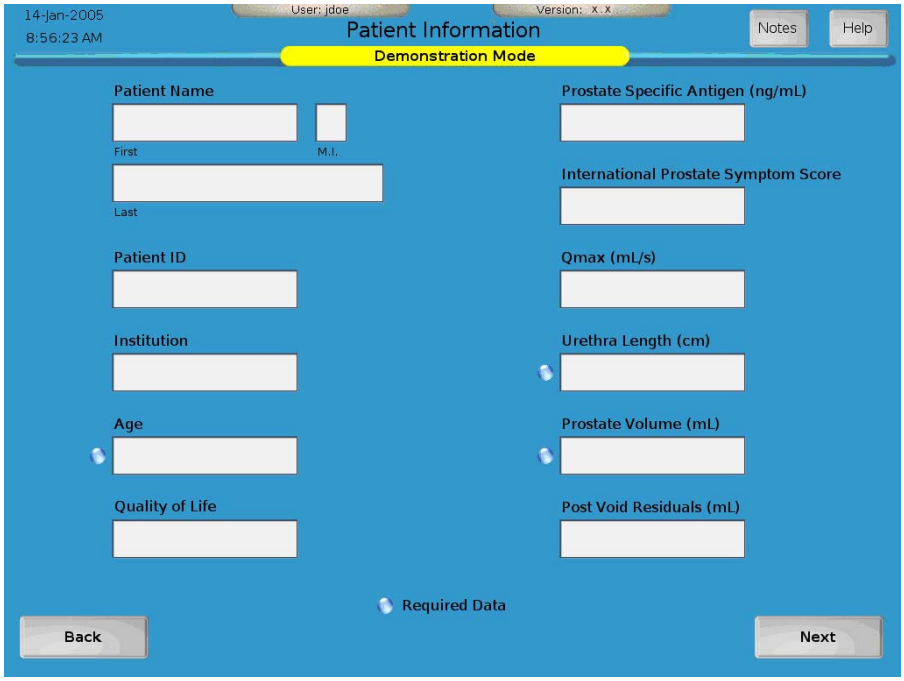


Figure 3-5. Example of a Treatment Screen in Demonstration Mode

3.1.2.1 Help

Note: If you receive an error message on the System Calibration screen, the System Error screen, or while on the Urologix® - BPH Treatment screen, press the **Help** button to view information about the displayed error message.

1. Press the **Help** button. The Help window (Figure 3-6) appears containing the appropriate help information based on your location in the CoolWave® Control Unit System software.

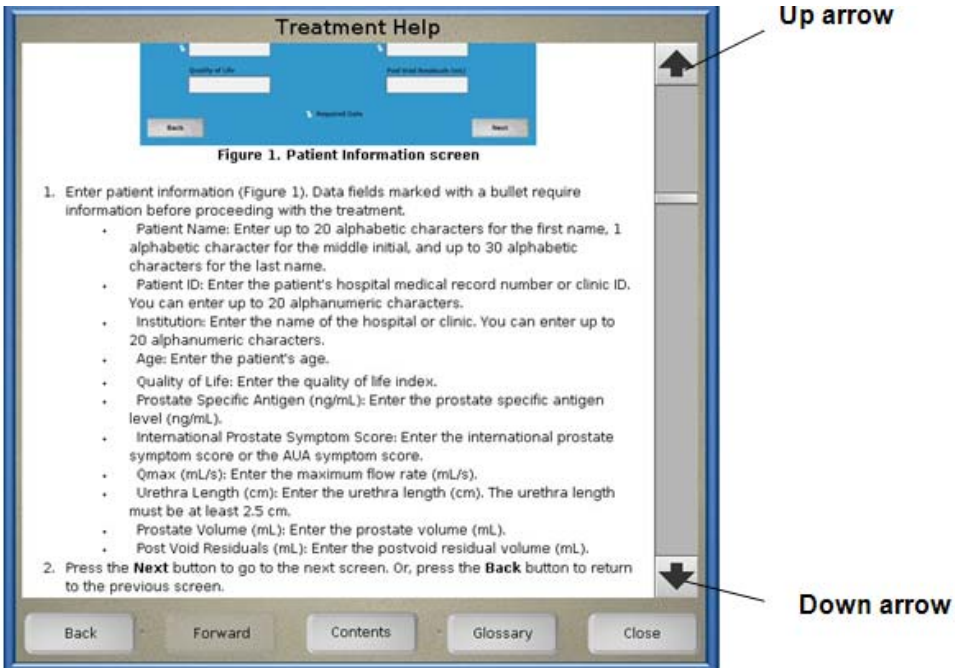

Treatment Help
Figure 1. Patient Information screen
1. Enter patient information (Figure 1). Data fields marked with a bullet require information before proceeding with the treatment.
• Patient Name: Enter up to 20 alphabetic characters for the first name, 1 alphabetic character for the middle initial, and up to 30 alphabetic characters for the last name.
• Patient ID: Enter the patient's hospital medical record number or clinic ID. You can enter up to 20 alphanumeric characters.
• Institution: Enter the name of the hospital or clinic. You can enter up to 20 alphanumeric characters.
• Age: Enter the patient's age.
• Quality of Life: Enter the quality of life index.
• Prostate Specific Antigen (ng/mL): Enter the prostate specific antigen level (ng/mL).
• International Prostate Symptom Score: Enter the international prostate symptom score or the AUA symptom score.
• Qmax (mL/s): Enter the maximum flow rate (mL/s).
• Urethra Length (cm): Enter the urethra length (cm). The urethra length must be at least 2.5 cm.
• Prostate Volume (mL): Enter the prostate volume (mL).
• Post Void Residuals (mL): Enter the postvoid residual volume (mL).
2. Press the Next button to go to the next screen. Or, press the Back button to return to the previous screen.
Back
Forward
Contents
Glossary
Close
Up arrow
Down arrow

Figure 3-6. Help Window

2. Press the up and down arrows to scroll through the Help window. Or, press the **Back**, **Forward**, **Contents**, **Glossary**, or **Close** buttons to move through the help feature.
   - Press the **Back** button: Move back through the help topics viewed recently.
   - Press the **Forward** button: Move forward through the help topics viewed recently.
   - Press the **Contents** button: View the CoolWave® Control Unit User Manual table of contents.
   - Press the **Glossary** button: View the CoolWave® Control Unit User Manual index glossary.
   - Press the **Close** button: Close the Help window.

3.1.2.2 Notes

1. Press the **Notes** button. The Notes dialog box appears (Figure 3-7).

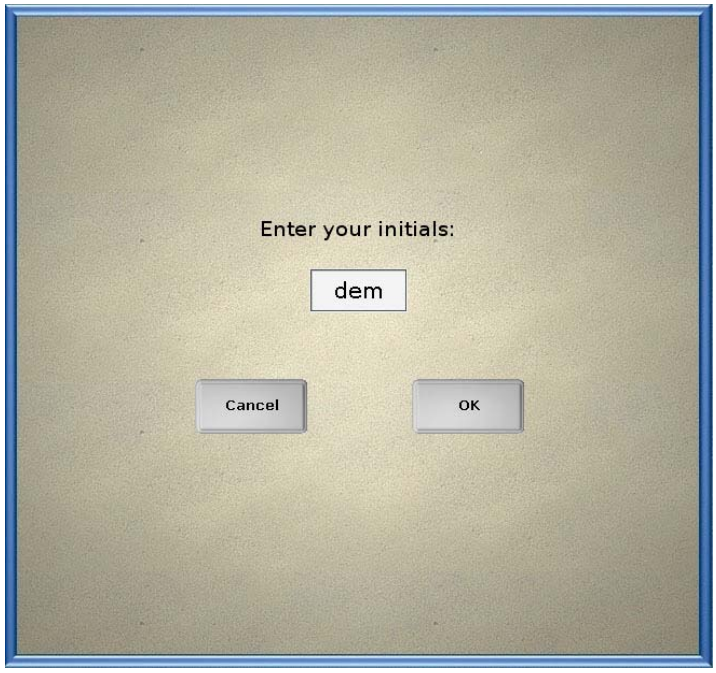


Figure 3-7. Notes Dialog Box

2. Enter your initials in the data field. You can use from 1 to 3 alphanumeric characters.
3. Press the **OK** button, and proceed to step 4. Or, press the **Cancel** button to exit the notes feature.
4. Enter patient treatment information in the Notes Entry window (Figure 3-8). Each time you access the notes feature throughout a treatment, you will see a date and time stamp, the elapsed time, and your initials. The elapsed time indicates the time since system calibration started, when you are on the System Calibration screen. Or, when on the Urologix® - BPH Treatment screen, the elapsed time indicates the time since the treatment started. If you have not started system calibration or a treatment, then the elapsed time will be 00:00.

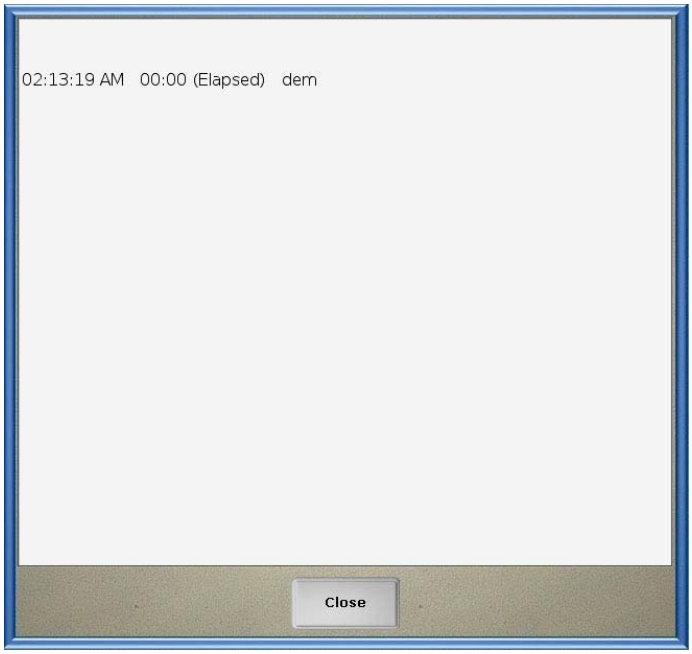


Figure 3-8. Notes Entry Window

5. Press the **Close** button when finished

3.2 CoolWave® Control Unit setup

Warning: Do not move the CoolWave Control Unit while the electrical cord is connected to a power source.

Note: Turn ON the Control Unit at least 5 minutes before the treatment begins to allow the system to warm up.

3.2.1 Turn ON the Control Unit

Press the ON/OFF power switch (located on the back of the unit, see Figure 1-6. ON/OFF power switch) to the "I" position. The CoolWave Control Unit turns ON and proceeds with its startup routine. The Login screen appears.

3.2.2 Login screen

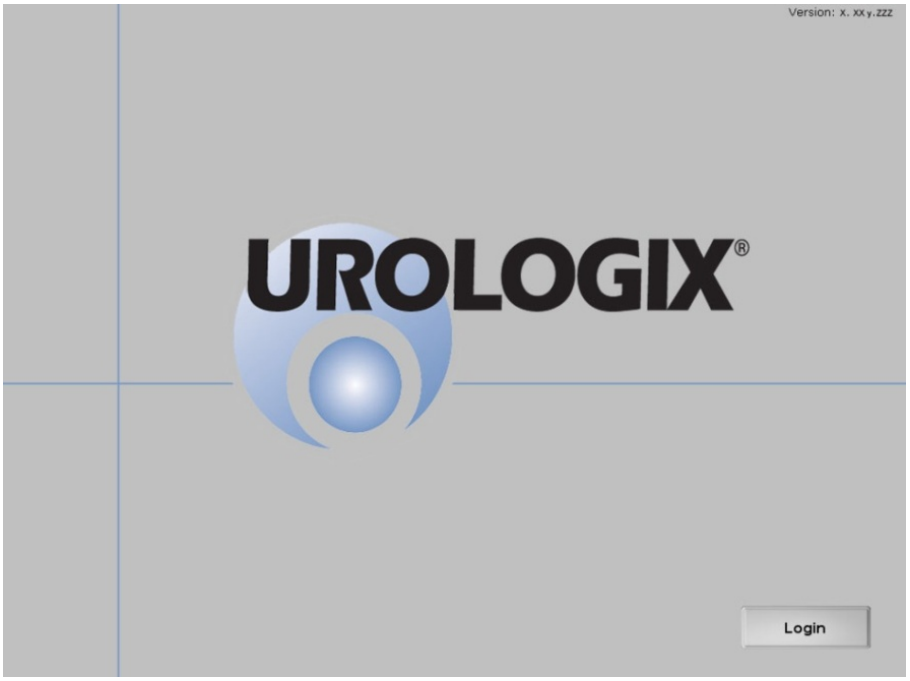


Figure 3-9. Login Screen

Notes:

- You can turn OFF the CoolWave® Control Unit at this point during system startup without losing any stored data.
- Entering an invalid password returns you to the Login screen.

1. Press the **Login** button (Figure 3-9). The User Login window appears (Figure 3-10).

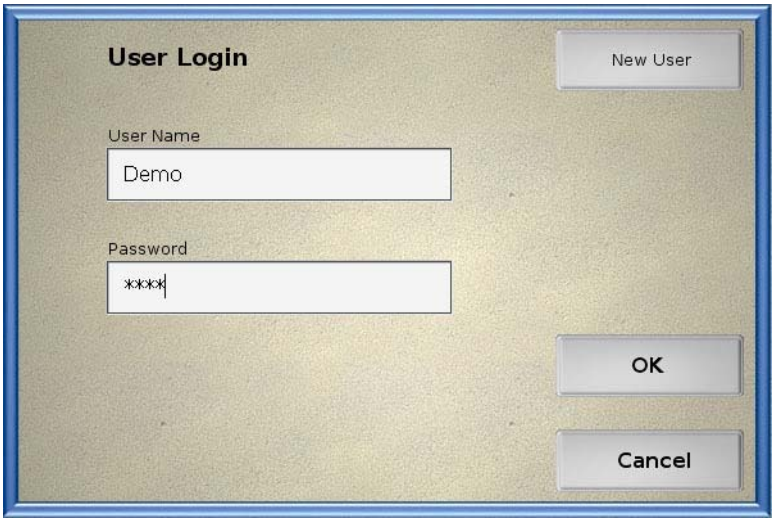


Figure 3-10. User Login Window

2. Determine if you are a new user or a current user. If you are a new user, proceed to step 3. If you are a current user, proceed to step 10.
3. Press the **New User** button. The Create New User window appears (Figure 3-11).
4. Enter your full name in the Full Name data field.

Figure 3-11. Create New User Window

5. Enter a user name in the User Name data field. Your user name, which is case sensitive, may contain from 3 to 20 alphanumeric characters.
6. Enter a password in the Password data field. Your password, which is case sensitive, may contain from 3 to 20 alphanumeric characters.
7. Re-enter your password in the Password Confirm data field.

8. Press the **OK** button to return to the Login screen. Your user name and password are saved. Proceed to step 9. Or, press the **Cancel** button to exit without creating a new user name and password.
9. Press the **Login** button (Figure 3-9). The User Login window appears (Figure 3-12).

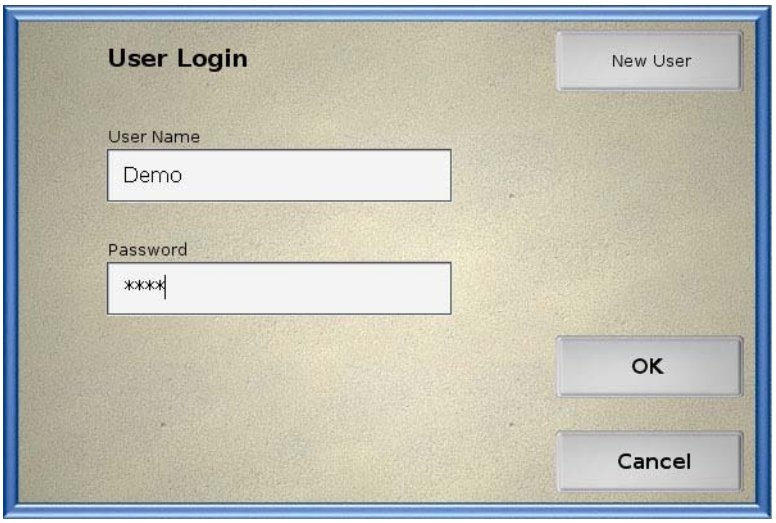


Figure 3-12. User Login Window

10. Enter your user name, which is case sensitive, in the User Name data field.
11. Enter your password, which is case sensitive, in the Password data field.
12. Press the **OK** button to go to the Main Menu screen. Or, press the **Cancel** button to return to the Login screen.

Demonstration mode

To enter demonstration mode, type the following word as the user name and the password: Demo. The capitalization of the letter "D" in Demo is required.

3.2.3 Main Menu Screen

After logging into the CoolWave® Control Unit, your user name and the software version appears at the top of the Main Menu screen (Figure 3-13).

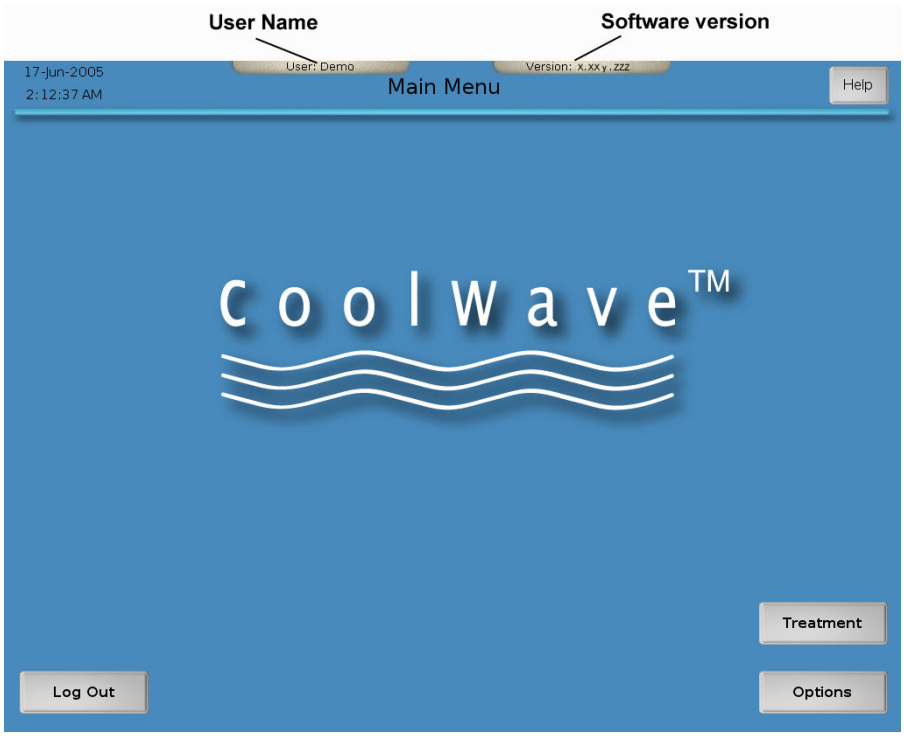


Figure 3-13. Main Menu Screen

Note: Turning OFF the Control Unit at this point during system startup does not cause a loss of stored data.

1. Press the **Treatment** button to proceed with a treatment. Refer to *Section 3.3, Cooled ThermoTherapy™ ,* for further information.
2. Press the **Options** button to view CoolWave Control Unit system options. Refer to *Section 3.5, CoolWave Control Unit options*, for further information.
3. Press the **Log Out** button to return to the Login screen. Refer to *Section 3.2.2, Login screen*, for further information.

3.3 Cooled ThermoTherapy™ Procedure

This section of the user manual steps you through a Cooled ThermoTherapy™ Procedure for Benign Prostatic Hyperplasia (BPH) using the CoolWave® Control Unit. As you proceed through the various treatment screens described in this section, beginning with the Patient Information screen, you will be entering data and selecting treatment protocols. You may also be modifying the following treatment parameters:

- Treatment time: The treatment time reflects the length of time for a Cooled ThermoTherapy Procedure. The default treatment time is 28 minutes and 30 seconds.
- Coolant setting: The coolant setting reflects the set point (target) temperature at which the coolant flows through the microwave catheter. The following table includes the default coolant setting temperature for the Targis® Microwave Catheter and the Cooled ThermoCath® Microwave Catheter and the CTC Advance® Microwave Catheter:

	Default coolant setting temperature
Targis® Microwave Catheter	8°C
CTC Advance® and Cooled ThermoCath® Microwave Catheter	15°C

The coolant temperature will ramp to its coolant setting temperature during a treatment.

- Urethra setting: The urethra setting reflects the set point (target) temperature of the microwave catheter. The default urethra setting temperatures for the Targis Microwave Catheter, the Cooled ThermoCath Microwave Catheter, and the CTC Advance® Microwave Catheter are 40°C.
- Ramp rate: The ramp rate reflects the speed at which the Microwave Catheter and coolant temperatures change from their current values to their set point (target) values.

Then, once you reach the System Calibration screen, the calibration process begins. After the calibration process completes, the CoolWave Control Unit enters the automatic treatment mode. To learn more about the automatic treatment mode, and the manual treatment mode, please refer to *Section 3.7, Treatment modes*, for further information. Otherwise, proceed to *Section 3.3.1, Patient Information screen*, to begin the Cooled ThermoTherapy procedure.

Safety Checks During Treatment

Important

It is critical that, throughout the patient's treatment, the treating physician verify the correct position of the microwave catheter and the RTU. Patient safety is at risk if the following simple and straightforward procedures are not correctly observed.

1. **Throughout the duration of the treatment, verify that the position mark on the catheter remains at a fixed distance from the penile meatus.**
2. **It is strongly recommended that at least every 5-10 minutes of the treatment, the correct position of the location balloon in the bladder be checked by transabdominal ultrasound. Document the action by placing the ultrasound in the permanent patient record.**
3. **Check the correct positioning of the rectal unit at least every 5 to 10 minutes to ensure the rectal unit has not moved.**
4. **Always immediately check microwave catheter and rectal unit placement if the patient complains of any abnormal or sudden increase in pain. Pause the treatment if the patient complains of serious pain.**

5. **Observe the treatment parameters for sudden changes in readings, especially decreases in temperatures that might indicate a sensor has moved from its previous position.**

Table 3-1. Safety Checks During Treatment

3.3.1 Patient Information screen

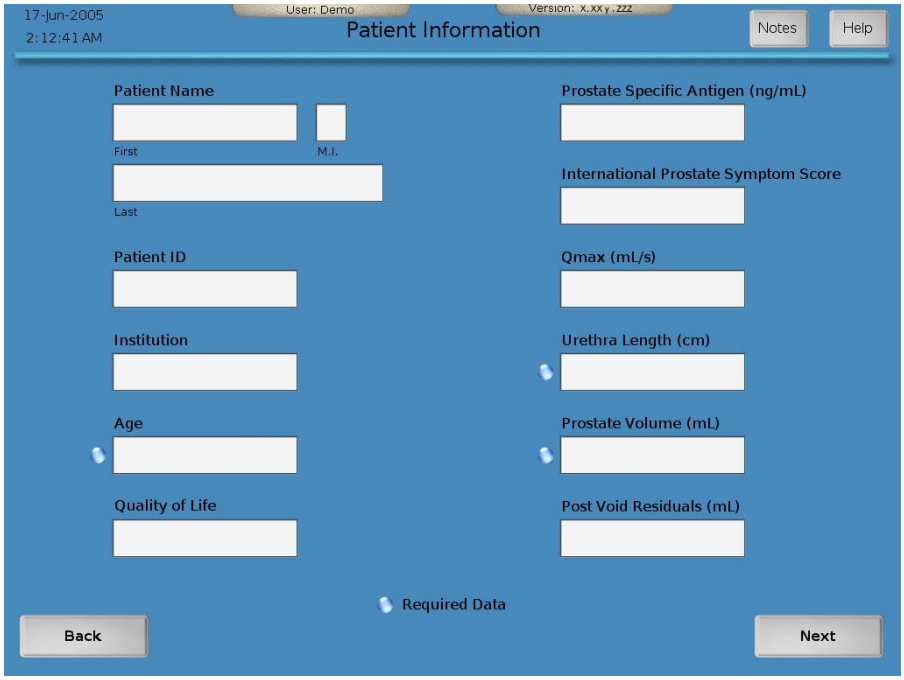


Figure 3-14. Patient Information Screen

1. Enter patient information (Figure 3-14). Data fields marked with a bullet require information before proceeding with the treatment.
   - Patient Name: Enter up to 20 alphabetic characters for the first name, 1 alphabetic character for the middle initial, and up to 30 alphabetic characters for the last name.
   - Patient ID: Enter the patient's hospital medical record number or clinic ID. You can enter up to 20 alphanumeric characters.
   - Institution: Enter the name of the hospital or clinic. You can enter up to 20 alphanumeric characters.
   - Age: Enter the patient's age.
   - Quality of Life: Enter the quality of life index.
   - Prostate Specific Antigen (ng/mL): Enter the prostate specific antigen level (ng/mL).
   - International Prostate Symptom Score: Enter the international prostate symptom score or the AUA symptom score.
   - Qmax (mL/s): Enter the maximum flow rate (mL/s).
   - Urethra Length (cm): Enter the urethra length (cm). The urethra length must be at least 2.5 cm.
   - Prostate Volume (mL): Enter the prostate volume (mL).

- Post Void Residuals (mL): Enter the postvoid residual volume (mL).

2. Press the **Next** button to go to the next screen. Or, press the **Back** button to return to the previous screen.

Demonstration mode

Enter "dummy" text on the Patient Information screen. Be sure to include information in the data fields marked with a bullet.

3.3.2 Protocol screen

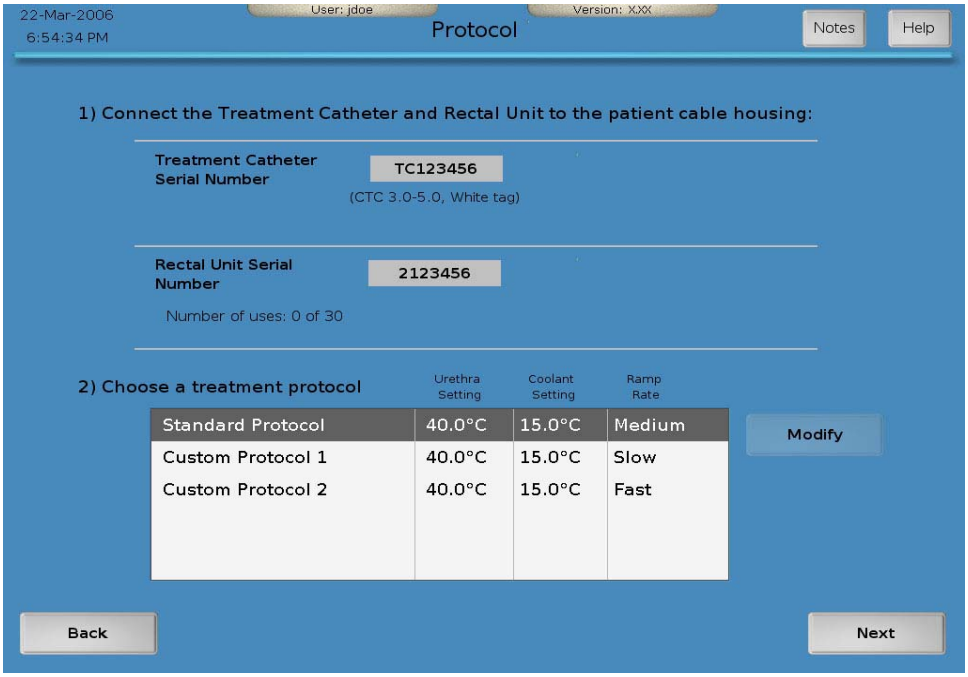


Figure 3-15. Example of a Protocol Screen

Note: The RTU Plus Reusable Handle should not be used in excess of 30 times.

1. Connect the microwave catheter and the rectal unit to the patient connection cable housing if you have not done so already (refer to *Section 2.9, Connecting the Microwave Catheter and Rectal Unit to the CoolWave® Control Unit*).
2. Verify that the CoolWave Control Unit automatically inserted the microwave catheter and rectal unit serial numbers in the appropriate data fields in step 1 on the Protocol screen (Figure 3-15).
   a) If both serial numbers appear in the data fields, proceed to step 3.
   b) If both serial numbers appear in the data fields, but the microwave catheter serial number indicates that a used catheter is connected to the system, a caution symbol appears. To use a new microwave catheter, refer to *Section 2.6, Inserting the microwave catheter*, for further information. Once a new microwave catheter is in place, the CoolWave Control Unit automatically reads the new serial number. Proceed to step 3.

c) If both serial numbers appear in the data fields, but the rectal unit serial number indicates that the rectal unit has exceeded its maximum number of uses, a caution symbol appears. To use a new rectal unit, refer to *Section 2.7, Inserting the Single-Use Standard RTU*, or *Section 2.8 , Inserting the RTU Plus Reusable Handle and Single-Use Balloon*, for further information. Once a new rectal unit is in place, the CoolWave® Control Unit automatically reads the new serial number. Proceed to step 3.

d) If one or both serial numbers do not appear in the data fields, then the treatment protocol list appears blank. Readjust the connectors, tags, and serial number labels (Figure 3-16) until the serial number(s) appear in the data field(s). Proceed to step 3.

Figure 3-16. Readjust connectors, tags, and serial number labels

Warning: Selection and use of the appropriate catheter model is required to assure patient safety. Verify that the correct catheter has been read by the Control Unit using the instructions provided in step 3.

3. Verify that the correct microwave catheter was read by the CoolWave Control Unit. The microwave catheter serial number and the description provided on the Protocol CoolWave screen must match the microwave catheter selected and inserted in the patient. The catheter can be verified using the information provided in Table 3-2.

Note: The serial number label is attached to the cable of the microwave catheter near the connection to the patient cable. See Figure 3-16.

Microwave Catheter	Prostatic Urethral Length	Catheter Color Scheme	Serial Number Tag Color	Serial Number Prefix
CTC Advance® - Short	2.5 to 3.5 cm	Blue Handle Black Accents	Black	TH
CTC Advance® or Cooled ThermoCath® - Standard	3.0 to 5.0 cm	Blue* Handle White Accents	White	TC
CTC Advance® or Cooled ThermoCath® - Long	≥ 4.5 cm	Blue* Handle Grey Accents	Grey	TF
Targis® - Short	2.5 to 3.5 cm	White Catheter Green Handle	Green	AB
Targis® - Standard	3.0 to 5.0 cm	White Catheter White Handle	Blue	AB

Table 3-2. Microwave catheter identification

*NOTE: A dark blue handle is Cooled ThermoCath®, the light blue is the CTC Advance®.

4. Select the desired treatment protocol, in step 2 on the Protocol screen, for your patient, and then press the treatment protocol name (Figure **3-15**). Protocols can vary depending on the microwave catheter in use and user preference. The description next to each protocol defines first the urethra temperature, second the coolant temperature, and third the ramp rate; all treatment times default to 28 minutes and 30 seconds, though that time can be modified from the standard mode or advanced mode CoolWave® Control Panel on the Urologix® - BPH Treatment screen. In addition, a custom protocol is user defined and can be modified. To modify a custom protocol, proceed to step 4. Otherwise, proceed to step 7 to continue with the treatment.
5. Select a custom protocol, if you have not done so already, by pressing on the treatment protocol name. Then, press the **Modify** button (Figure 3-17).

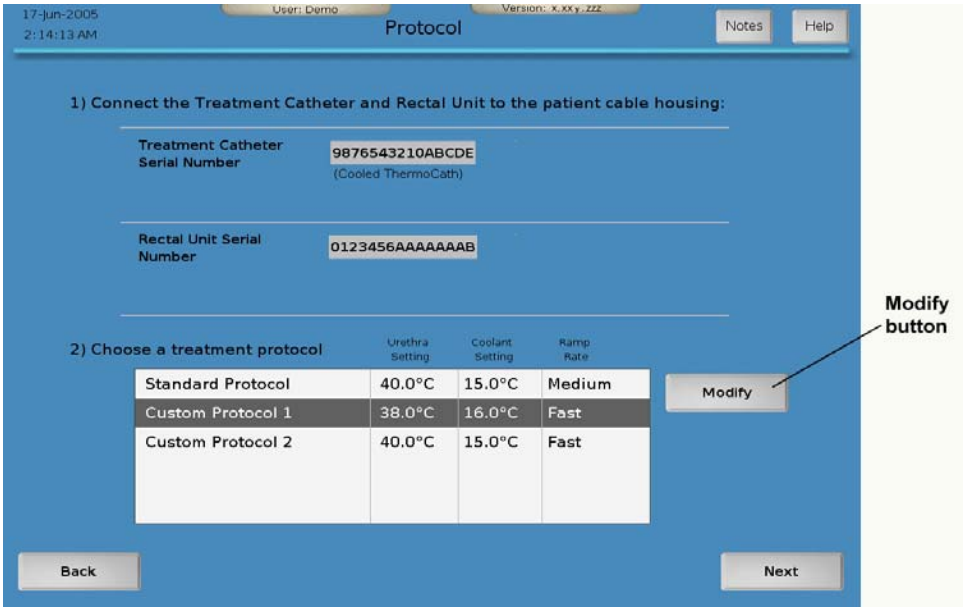


Figure 3-17. Example of Protocol screen - modify

6. Adjust the urethra setting, coolant setting, and ramp rate (Figure 3-18), as desired:

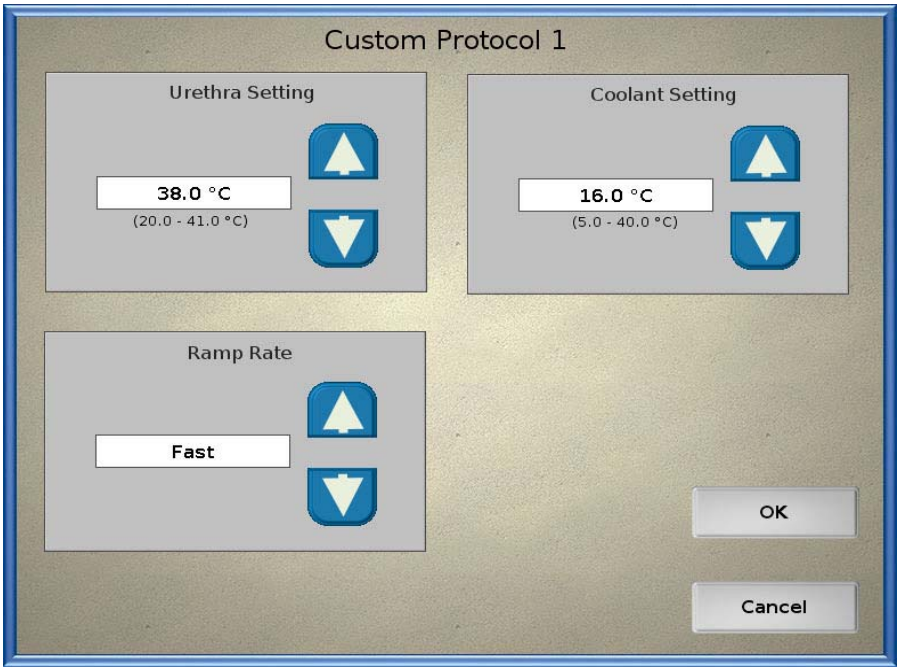


Figure 3-18. Example of treatment protocol - modify

Note: The treatment timer runs when the following conditions occur:

Targis® Short & Standard	CTC Advance® Short	CTC Advance® Cooled ThermoCath® Standard & Long
• Urethra ≥ **35**°C, with (Urethra - Coolant) difference ≥ **23**°C • OR: MW Power ≥ **50** W • OR: RTU ≥ **41**°C	• Urethra ≥ **35**°C, with (Urethra - Coolant) difference ≥ **20**°C • OR: MW Power ≥ **50** W • OR: RTU ≥ **41**°C	• Urethra ≥ **35**°C, with (Urethra - Coolant) difference ≥ **20**°C • OR: MW Power ≥ **65** W • OR: RTU ≥ **41**°C

Table 3-3 Treatment Timer algorithms

a) Urethra setting: Press the up and down arrows to adjust the urethra setting temperature in 0.5°C increments. The default urethra setting temperatures for the Targis Microwave Catheter and the Cooled ThermoCath microwave catheter and the CTC Advance® Microwave Catheter are 40°C.

b) Coolant setting: Press the up and down arrows to adjust the coolant setting temperature in 0.5°C increments. The following table includes the default coolant setting temperature for the Targis Microwave Catheter, the Cooled ThermoCath Microwave Catheter and the CTC Advance® Microwave Catheter:

	Default coolant setting temperature
Targis® Microwave Catheter	8°C
CTC Advance® and Cooled ThermoCath® Microwave Catheter	15°C

The coolant temperature will ramp to its coolant setting temperature during a treatment.

c) Ramp rate: Press the up and down arrows to select the ramp rate: slow / medium / fast, (approximately 12 / 8 / 4 minutes)

7. Press the **OK** button to save the new treatment parameter(s). Or, press the **Cancel** button to return to the original treatment parameters for that protocol.
8. Press the **Next** button to go to the next screen. Or, press the **Back** button to return to the previous screen.

Demonstration mode

The CoolWave® Control Unit will automatically fill in the microwave catheter serial number and rectal unit serial number data fields with simulated information. Start with step 4 above.

3.3.3 Treatment Checklist screen

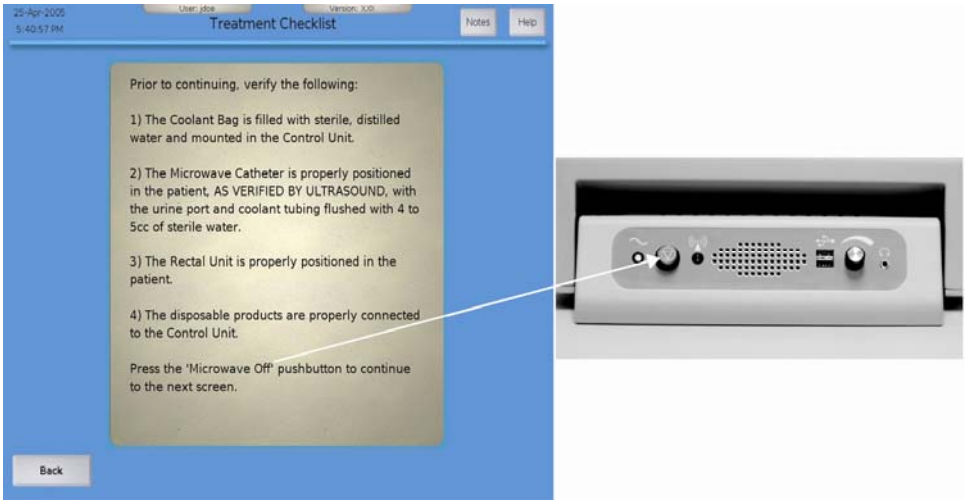

Treatment Checklist
Notes
Help
Prior to continuing, verify the following:
1) The Coolant Bag is filled with sterile, distilled water and mounted in the Control Unit.
2) The Microwave Catheter is properly positioned in the patient, AS VERIFIED BY ULTRASOUND, with the urine port and coolant tubing flushed with 4 to 5cc of sterile water.
3) The Rectal Unit is properly positioned in the patient.
4) The disposable products are properly connected to the Control Unit.
Press the 'Microwave Off' pushbutton to continue to the next screen.
Back

Figure 3-19. Treatment Checklist screen and Microwave Off pushbutton

1. Read the Treatment Checklist screen for information about the treatment (Figure 3-19). Prior to continuing this treatment, verify that all of these steps are complete.
2. Follow the instructions on the Treatment Checklist screen to go to the next screen. Or, press the **Back** button to return to the previous screen.

Note: When you press the **Microwave Off** pushbutton on the CoolWave® Control Unit, the system will confirm that the **Microwave Off** pushbutton functions properly.

Demonstration mode

When in demonstration mode, you will not press the **Microwave Off** pushbutton. Instead, press the **Microwave Off** button on the Treatment Checklist screen (Figure 3-20).

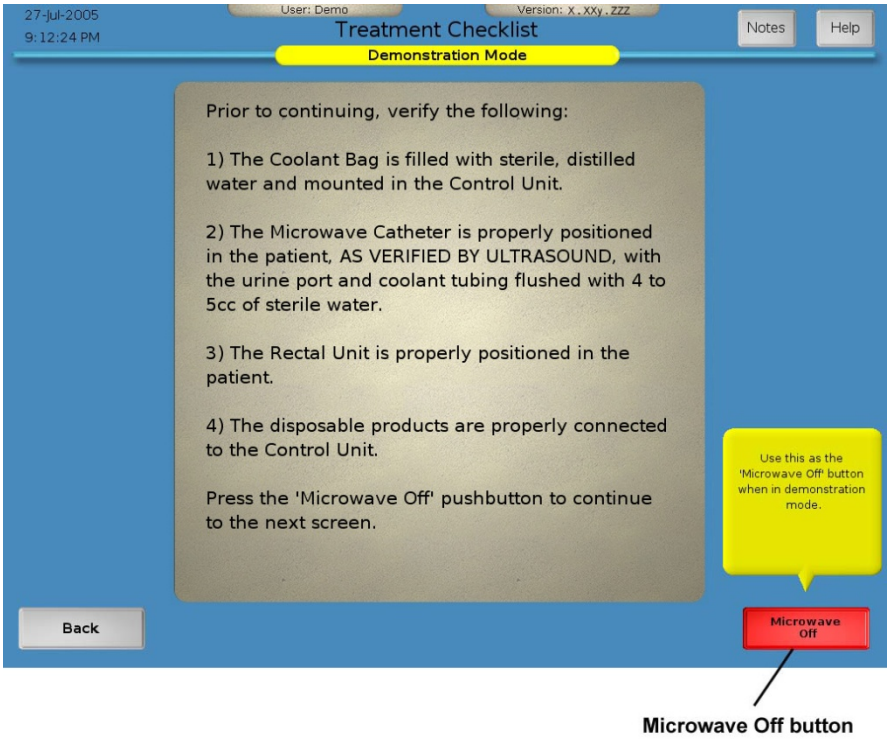

27-Jul-2005
9:12:24 PM
User: Demo
Version: X.XXy.ZZZ
Treatment Checklist
Notes
Help
Demonstration Mode
Prior to continuing, verify the following:
1) The Coolant Bag is filled with sterile, distilled water and mounted in the Control Unit.
2) The Microwave Catheter is properly positioned in the patient, AS VERIFIED BY ULTRASOUND, with the urine port and coolant tubing flushed with 4 to 5cc of sterile water.
3) The Rectal Unit is properly positioned in the patient.
4) The disposable products are properly connected to the Control Unit.
Press the 'Microwave Off' pushbutton to continue to the next screen.
Use this as the 'Microwave Off' button when in demonstration mode.
Back
Microwave Off
Microwave Off button

Figure 3-20. Treatment Checklist screen - Demonstration mode

3.3.4 System Calibration screen

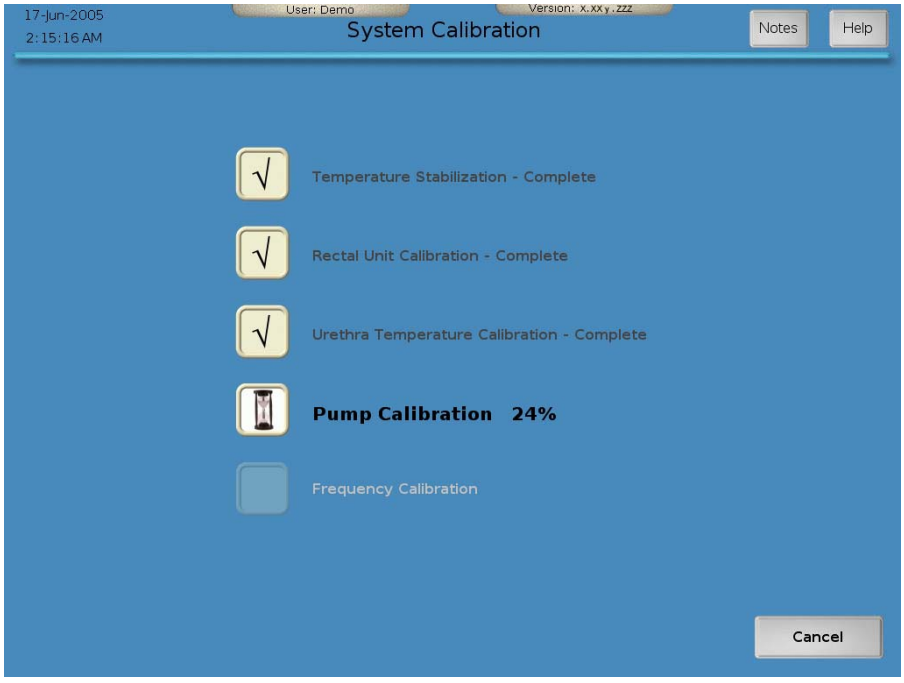


Figure 3-21. System Calibration screen

1. Wait while the Control Unit proceeds through a calibration process (can take up to 7 minutes) (Figure **3-21**):

- Temperature stabilization
- Rectal unit calibration
- Urethra temperature calibration
- Pump calibration
- Frequency calibration

As each item in the list completes calibration, a checkmark appears in the box next to that item.

a) Calibration completes successfully: Proceed to *Section 3.3.5, Urologix® - BPH Treatment screen*, if the Control Unit completes the calibration process and automatically goes to the Urologix - BPH Treatment screen.
b) Calibration does not complete successfully: An error message appears on the System Calibration screen. Proceed to step 2.
c) Calibration needs to stop due to user needs: Press the **Cancel** button to stop the calibration process. An error message appears on the System Calibration screen. Proceed to step 2.

2. Read the System Calibration screen (Figure 3-22), and use the error message to resolve the problem. In addition, use one of the actions listed on the System Calibration screen to help you determine what to do next.

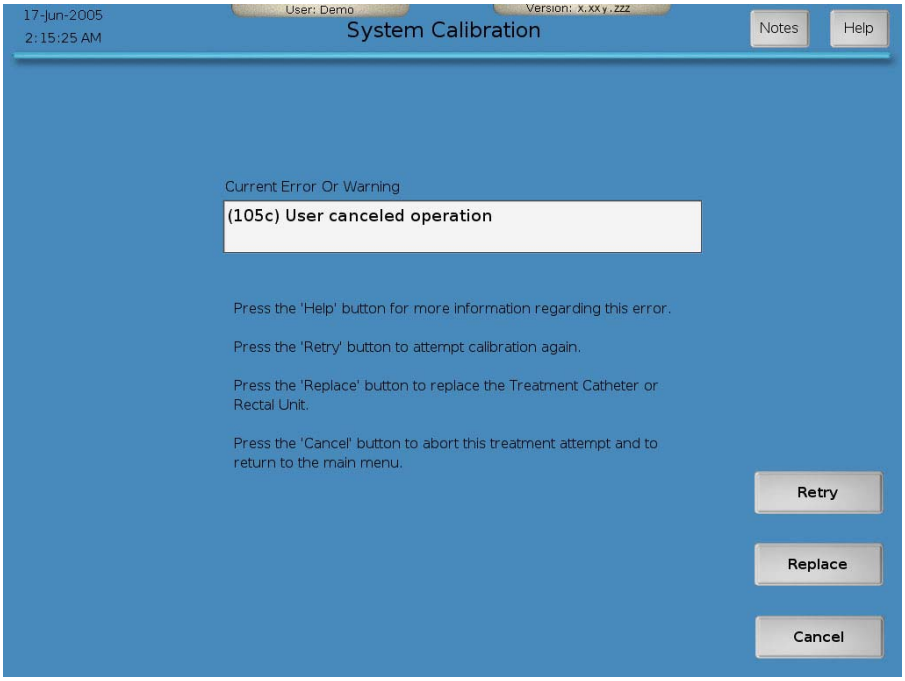

17-Jun-2005
2:15:25 AM
User: Demo
Version: x.xxy.zzz
System Calibration
Notes
Help
Current Error Or Warning
(105c) User canceled operation
Press the 'Help' button for more information regarding this error.
Press the 'Retry' button to attempt calibration again.
Press the 'Replace' button to replace the Treatment Catheter or Rectal Unit.
Press the 'Cancel' button to abort this treatment attempt and to return to the main menu.
Retry
Replace
Cancel

Figure 3-22. System Calibration Screen - Error Message

Notes:

- If a calibration error message appears, refer to *Section 5.1, Troubleshooting guide*, for further information.

- Before replacing a microwave catheter or rectal unit, contact Urologix Customer Service at 1-888-229-0772.

a) Press the **Help** button: Learn more about the error message and the appropriate response.
b) Press the **Retry** button: Attempt the calibration process again.
c) Press the **Replace** button: Replace the microwave catheter or the rectal unit, as needed. Refer to *Section 2.6, Inserting the microwave catheter*, *Section 2.7, Inserting the Single-Use Standard RTU*, or *Section 2.8, Inserting the RTU Plus Reusable Handle and Single-Use Balloon*, for further information. The CoolWave Control Unit returns you to the Protocol screen. Refer to *Section 3.3.2, Protocol screen*, for further information.
d) Press the **Cancel** button: Exit this treatment, and return to the Main Menu screen.

3.3.5 Urologix® - BPH Treatment screen

The Urologix - BPH Treatment screen allows you to monitor patient progress during the procedure. If you need to make any adjustments to the treatment parameters, make those adjustments from this screen. Otherwise, treatment proceeds automatically based on the selected treatment protocol. If a caution or error occurs during treatment, a caution icon or error icon appears in the blue bar at the top of the screen (Figure 3-23). If there is an emergency, press the red **Microwave Off** pushbutton (Figure 3-24), located under the touchscreen monitor and right of the green LED, to immediately turn the microwave power OFF.

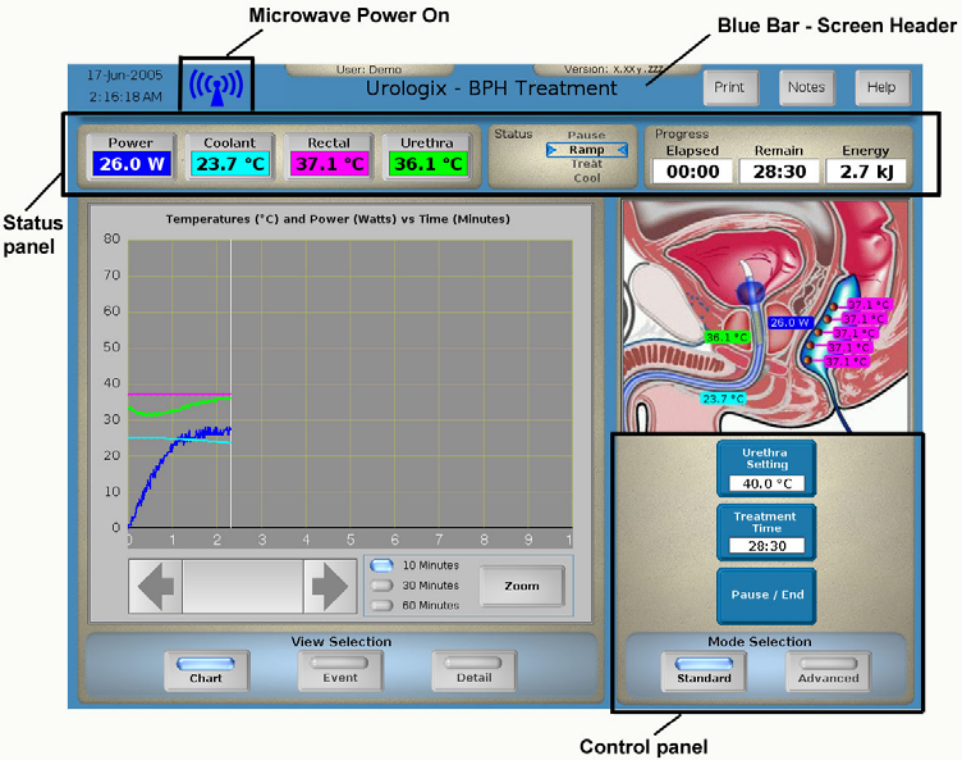


Figure 3-23. Urologix - BPH Treatment screen

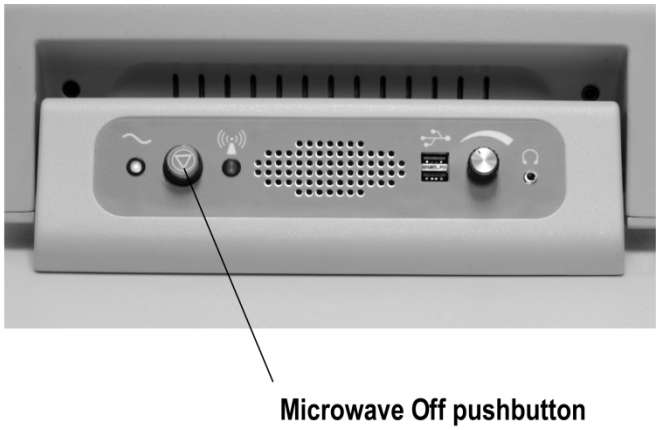


Figure 3-24. Microwave Off Pushbutton

1. View treatment data in the Status Panel at the top of the Urologix® - BPH Treatment screen (Figure 3-23).
   - Power: Displays microwave power in watts, measured at the patient connection cable. When power is ≥1 W, an animated microwave power ON graphic appears and the amber LED, located to the right of the red **Microwave Off** pushbutton, lights.
   - Coolant: Displays coolant temperature in °C as measured by the Coolant Bag sensor. If the coolant pump is turned OFF, this reading will gradually approach room temperature.
   - Rectal: Displays the warmest of the 5 rectal temperatures in °C.
   - Urethra: Displays the urethra temperature in °C.
   - Status: Highlights status as pause (treatment OFF), ramp (system preparing for treatment), treat (treatment ON), or cool (cooldown ON).
   - Progress: Displays treatment time (minutes:seconds) elapsed, treatment time (minutes:seconds) remaining, and energy (kilojoules). Treatment time elapsed, also referred to as the treatment timer, is defined by the following algorithms:

Targis® Short & Standard	CTC Advance® Short	CTC Advance® Cooled ThermoCath® Standard & Long
• Urethra ≥ **35** °C, with (Urethra - Coolant) difference ≥ **23** °C • OR: MW Power ≥ **50** W • OR: RTU ≥ **41** °C	• Urethra ≥ **35** °C, with (Urethra - Coolant) difference ≥ **20** °C • OR: MW Power ≥ **50** W • OR: RTU ≥ **41** °C	• Urethra ≥ **35** °C, with (Urethra - Coolant) difference ≥ **20** °C • OR: MW Power ≥ **65** W • OR: RTU ≥ **41** °C

Table 3-4. Treatment Timer algorithms

   Treatment time remaining is calculated by subtracting the current elapsed treatment time from the treatment time setting. You can tell, from the time remaining, when the CoolWave® Control Unit will enter cooldown.

2. View treatment details at the left side of the Urologix® - BPH treatment screen.
   a) Press the **Chart** button: View the microwave power, coolant temperature, rectal temperature, and urethra temperature for this treatment in a scrolling strip chart format (Figure 3-25). The colors of each trace on the chart correspond to the color of the item

in the Status Panel: The white vertical line indicates the current values and the end of the chart. Press the left and right arrows to scroll left and right through the chart. The **Zoom** button allows you to view this information in a 10 minute view, a 30 minute view, or a 60 minute view.

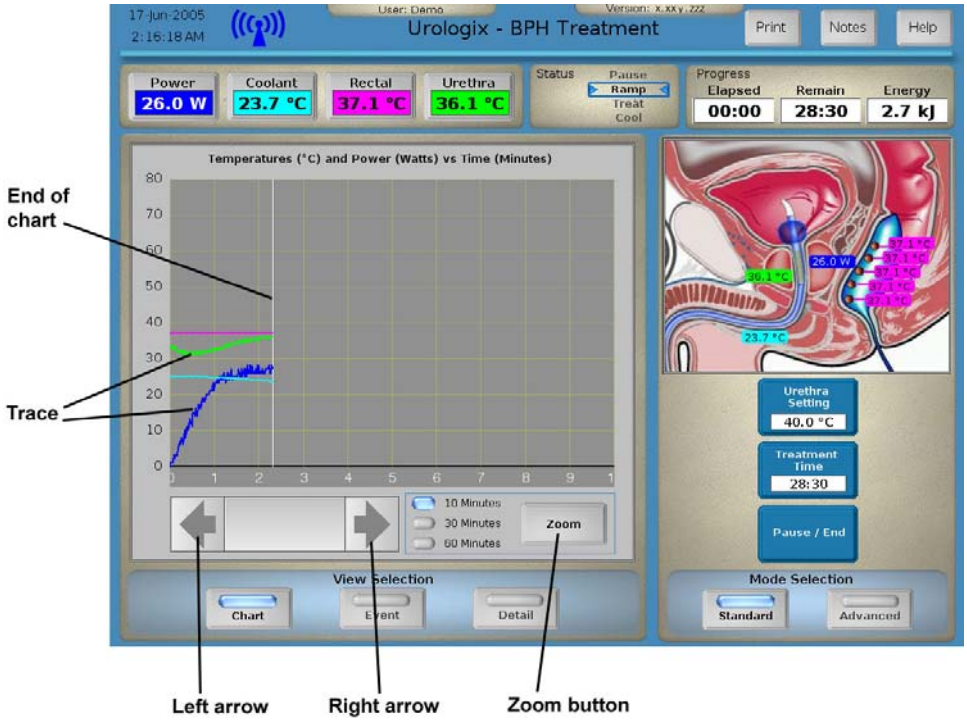


Figure 3-25. Chart pane

b) Press the **Event** button: View the treatment event log: events, errors, and warnings (Figure 3-26). Press the up and down arrows to scroll through the log. You can also view the current error or warning (listed in priority order, errors first) in the Current Error or Warning window. To reset current errors and warnings, press the **Reset** button. If the system does not return to the treatment and an error remains, refer to *Section 5.1, Troubleshooting guide*, for further information. For additional information about system errors, refer to *Section 3.6, System errors*.

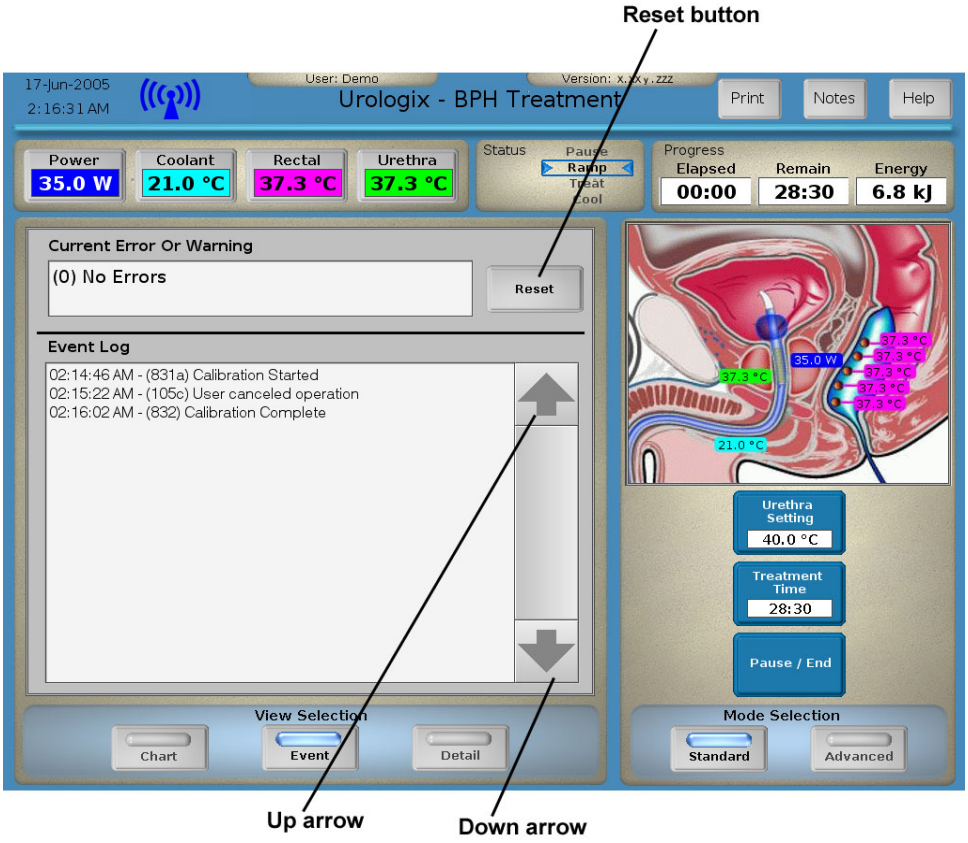


Figure 3-26. Event pane

c) Press the **Detail** button: View a detailed overview of the microwave power, coolant temperature, rectal temperature, and urethra temperature for this treatment (Figure 3-27). This overview also highlights current warnings and errors: An active error is marked with a blue light. To reset warnings and errors, press the **Reset** button. For additional information about system errors, refer to *Section 3.6, System errors*.

Note: The **Detail** button provides a detailed overview of the CoolWave® Control Unit and its settings. A typical treatment does not require access to this overview. However, you may need to view this information if an error occurs and does not resolve. At this point, contact Urologix® Customer Service (1-888-229-0772) to help you resolve any remaining errors.

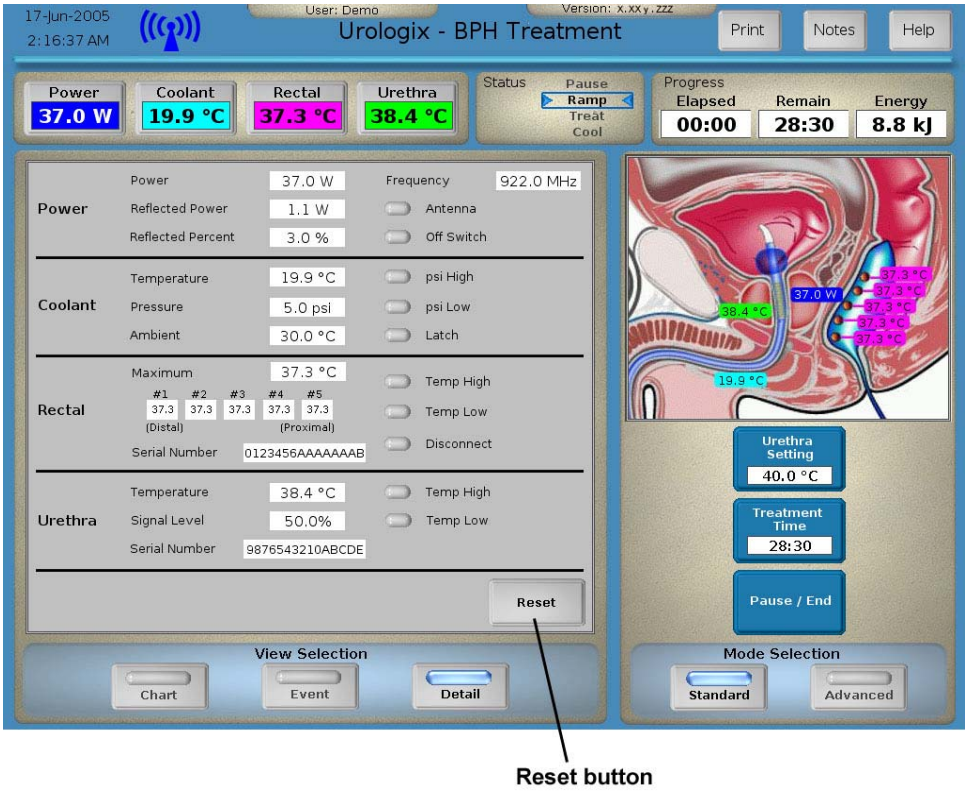


Figure 3-27. Detail pane

3. View treatment data in a diagram format at the right side of the Urologix® - BPH Treatment screen (Figure 3-28).

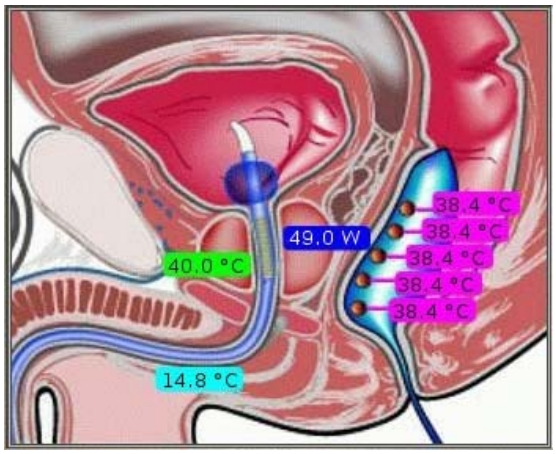


Figure 3-28. Treatment diagram

4. Press the **Print** button, located in the upper right corner of the Urologix - BPH Treatment screen. Then, select one of the following print options: Print Treatment Report, Print Event Log, and Clear Print Queue (Figure 3-29). Or, press the **Close** button to return to the Urologix - BPH Treatment screen.

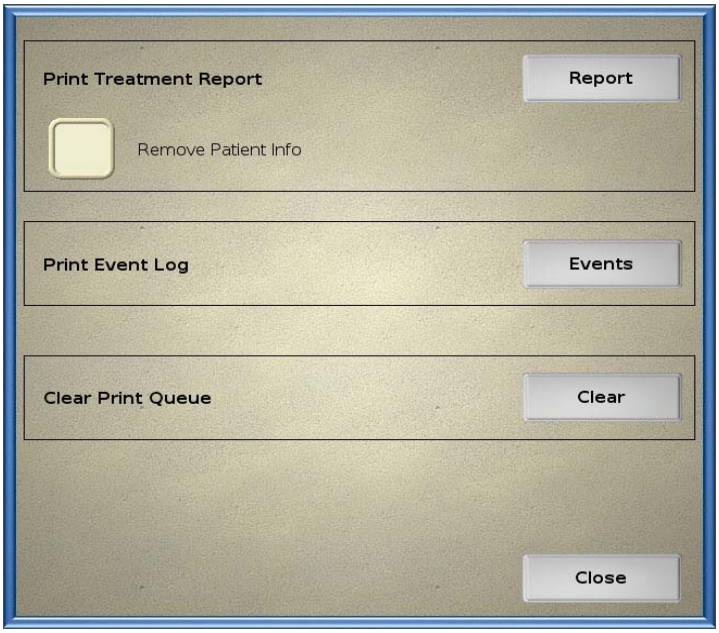


Figure 3-29. Print window

Note: Refer to *Section 4.3, Maintaining the printer*, **Figure 4-3**, for a printer overview.

a) Print Treatment Report: Press the **Remove Patient Info** button (optional) to remove a patient's name from a treatment report. A check mark appears in the button. Turn the printer ON, load paper, if needed, into the printer, and press the **Report** button. (However, if you pressed the **Report** button and paper was not in the printer, the printer flashes 1 long green and 2 short orange lights. Insert paper into the printer, and press the Resume/Cancel button on the printer.) The CoolWave® Control Unit automatically returns to the Urologix® - BPH Treatment screen while the treatment report prints. The report includes the following information:
   - Patient data
   - Treatment protocol data
   - Treatment data
   - Treatment chart
   - Event log
   - Case notes

b) Print Event Log: Turn the printer ON, load paper, if needed, into the printer, and press the **Events** button to print the event log. (However, if you pressed the **Events** button and paper was not in the printer, the printer flashes 1 long green and 2 short orange lights. Insert paper into the printer, and press the Resume/Cancel button on the printer.) The CoolWave Control Unit automatically returns to the Urologix - BPH Treatment screen while the event log prints.

c) Clear Print Queue: Press the **Clear** button to clear the print queue. The CoolWave Control Unit automatically returns to the Urologix - BPH Treatment screen while the print queue clears.

5. Select one of the following options to view and adjust treatment parameters:
   a) Press the **Standard** button on the Control Panel: View the controls for the urethra temperature and the treatment time. Refer to *Section 3.3.5.1, Using standard mode*, for further information.
   b) Press the **Advanced** button on the Control Panel: View the controls for the urethra temperature, treatment time, coolant temperature, and ramp rate. Refer to *Section 3.3.5.2, Using advanced mode*, for further information.
   c) Press the **Manual** button on the Control Panel: View the controls for microwave power, coolant pump ON/OFF, coolant temperature, and ramp rate. Refer to *Section 3.3.5.3, Using manual mode*, for further information.

   Note: If you do not have access to the manual treatment mode, you will not see this option on the Control Panel.
6. Press the **Pause/End** button on the Control Panel to pause a treatment or end a treatment early (before the treatment time expires). Refer to *Section 3.3.5.4, Pausing a treatment or ending a treatment early*, for further information.
7. Continue with the treatment until the treatment time ends and the Treatment Cooldown window (Figure 3-30) appears: Treatment is now complete. Refer to *Section 3.3.5.5, Ending a treatment*, for further information.

Figure 3-30. Treatment Cooldown window

3.3.5.1 Using standard mode

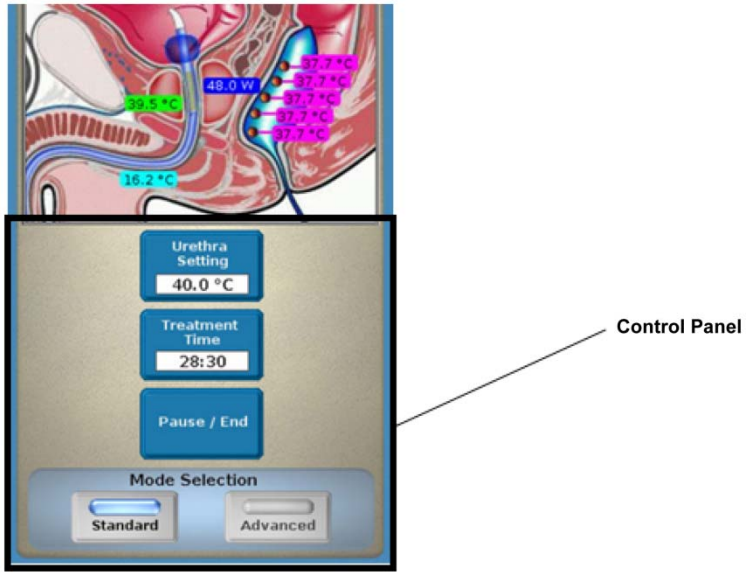


Figure 3-31. Standard mode

Adjust the urethra setting and treatment time from the Control Panel (Figure 3-31), if desired:

Note: The treatment timer runs when the following conditions occur:

Targis® Short & Standard	CTC Advance® Short	CTC Advance® Cooled ThermoCath® Standard & Long
• Urethra ≥ **35** ℃, with (Urethra - Coolant) difference ≥ **23** ℃ • OR: MW Power ≥ **50** W • OR: RTU ≥ **41** ℃	• Urethra ≥ **35** ℃, with (Urethra - Coolant) difference ≥ **20** ℃ • OR: MW Power ≥ **50** W • OR: RTU ≥ **41** ℃	• Urethra ≥ **35** ℃, with (Urethra - Coolant) difference ≥ **20** ℃ • OR: MW Power ≥ **65** W • OR: RTU ≥ **41** ℃

Table 3-5 Treatment Timer algorithms

- Press the **Urethra Setting** button: Press the up and down arrows to adjust the urethra setting temperature in 0.5°C increments. The default urethra setting temperatures for the Targis Microwave Catheter and the Cooled ThermoCath Microwave Catheter and the CTC Advance Microwave Catheter are 40°C. Press the **Close** button when done.
- Press the **Treatment Time** button: Press the up and down arrows to adjust the treatment time in 30 second increments. Press the **Close** button when done.

Note: In automatic treatment mode, the treatment time is limited to 28 minutes and 30 seconds for the Cooled ThermoCath Microwave catheter and from 28 minutes and 30 seconds to 60 minutes for the Targis Microwave catheter.

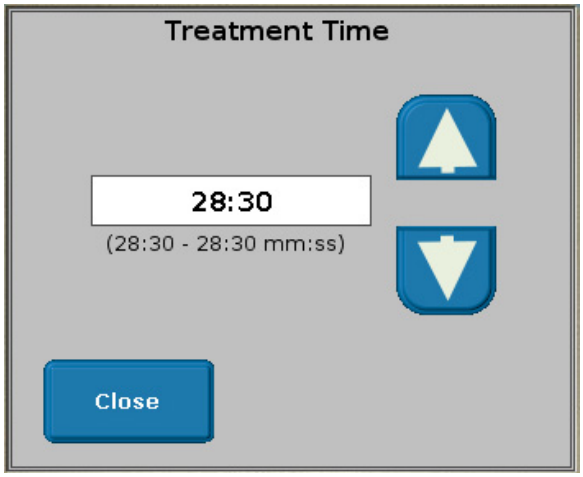


Figure 3-32. Example of a treatment parameter control panel

3.3.5.2 Using advanced mode

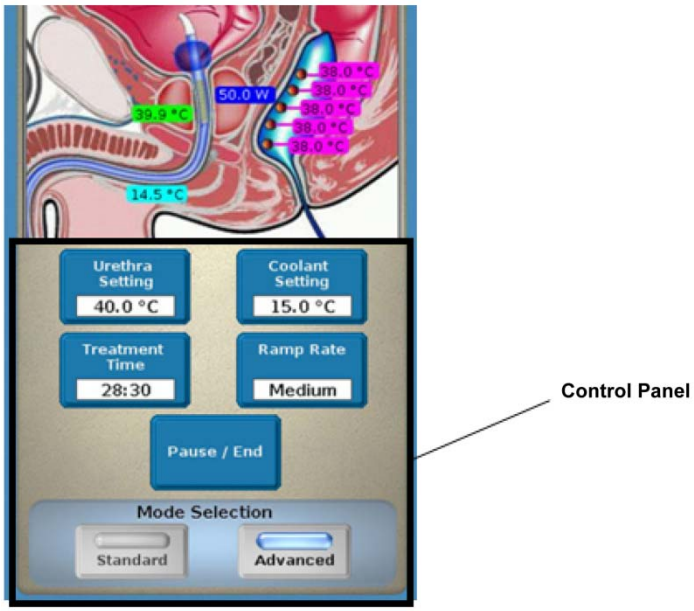


Figure 3-33. Advanced mode

Adjust the urethra setting, treatment time, coolant setting, and ramp rate from the Control Panel (Figure 3-33), if desired:

Note: The treatment timer runs when the following conditions occur:

Targis® Short & Standard	CTC Advance® Short	CTC Advance® Cooled ThermoCath® Standard & Long
• Urethra ≥ **35**°C, with (Urethra - Coolant) difference ≥ **23**°C • OR: MW Power ≥ **50** W • OR: RTU ≥ **41**°C	• Urethra ≥ **35**°C, with (Urethra - Coolant) difference ≥ **20**°C • OR: MW Power ≥ **50** W • OR: RTU ≥ **41**°C	• Urethra ≥ **35**°C, with (Urethra - Coolant) difference ≥ **20**°C • OR: MW Power ≥ **65** W • OR: RTU ≥ **41**°C

- Press the **Urethra Setting** button: Press the up and down arrows to adjust the urethra setting temperature in 0.5°C increments. The default urethra setting temperatures for the Targis Microwave Catheter and the Cooled ThermoCath Microwave Catheter and the CTC Advance Microwave Catheter are 40°C. Press the **Close** button when done.
- Press the **Treatment Time** button: Press the up and down arrows to adjust the treatment time in 30 second increments. Press the **Close** button when done.

Note: In automatic treatment mode, the treatment time is limited to 28 minutes and 30 seconds for the Cooled ThermoCath Microwave Catheter and CTC Advance Microwave Catheter from 28 minutes and 30 seconds or 60 minutes for the Targis Microwave catheter.

- Press the **Coolant Setting** button: Press the up and down arrows to adjust the coolant setting temperature in 0.5°C increments. The following table includes the default coolant setting temperature for the Targis® Microwave Catheter and the Cooled ThermoCath® Microwave Catheter and CTC Advance Microwave Catheter:

	Default coolant setting temperature
Targis® Microwave Catheter	8°C
CTC Advance® and Cooled ThermoCath® Microwave Catheter	15°C

The coolant temperature will ramp to its coolant setting temperature during a treatment. Press the **Close** button when done.

- Press the **Ramp Rate** button: Press the up and down arrows to select the ramp rate: slow, medium, fast. Press the **Close** button when done.

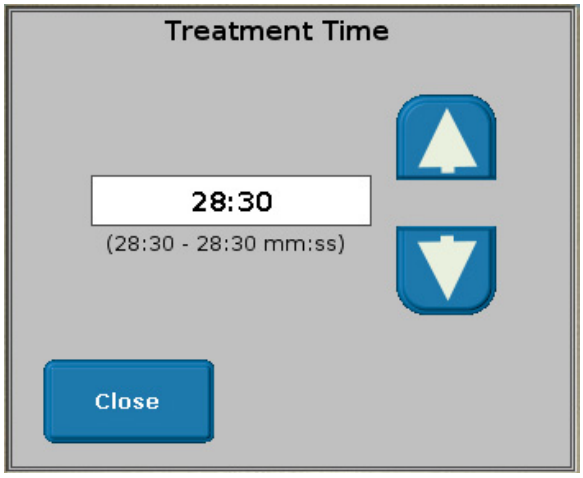


Figure 3-34. Example of a treatment parameter control panel

3.3.5.3 Using manual mode

When the manual treatment mode is active, the interval timer will appear on the Status Panel. This timer indicates the amount of time elapsed since you last adjusted microwave power and can be used to help you in timing a manual treatment. Refer to *Section 3.7.2, Manual treatment mode*, for further information on using the manual treatment mode.

Note: If you do not have access to the manual treatment mode, you will not see this option on the Control Panel.

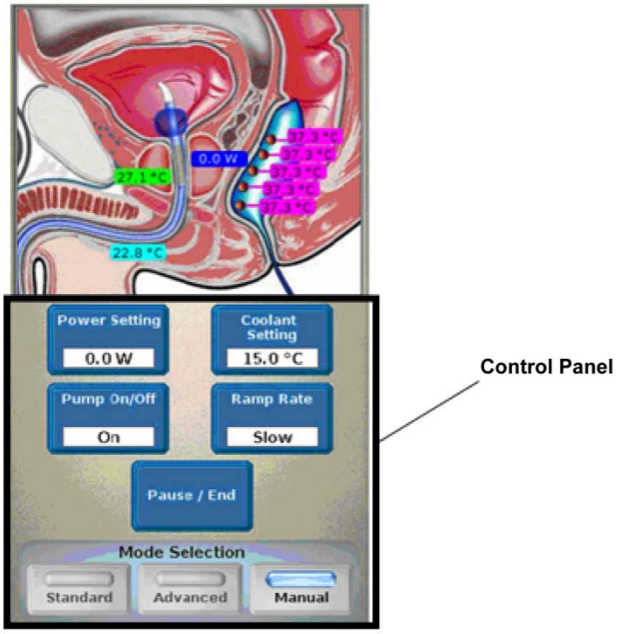


Figure 3-35. Manual mode

1. Select "Yes" or "No" when the Enter Manual Mode dialog box appears. Proceed to step 2 if entering the manual treatment mode (selecting "No" returns you to the Urologix® - BPH Treatment screen).
2. Adjust the power setting, pump ON/OFF, coolant setting, and ramp rate from the Control Panel (Figure 3-35), if desired:
    a) Press the **Power Setting** button: Press the up and down arrows to adjust the microwave power setting (from 0.0 W to 60.0 W for a Targis® and CTC Advance® Short Microwave Catheters, and from 0.0 W to 75.0 W for a Cooled ThermoCath® and CTC Advance® Standard and Long Microwave Catheters) in 1 W increments. Press the **Close** button when done.
    b) Press the **Pump On/Off** button: Press the up and down arrows to turn the coolant pump ON or OFF. In addition, if microwave power was ON when turning the pump OFF, microwave power will automatically turn OFF as well. Press the **Close** button when done.
    c) Press the **Coolant Setting** button: Press the up and down arrows to adjust the coolant setting temperature in 0.5°C increments. The following table includes the default coolant setting temperature for the Targis Microwave Catheter and the Cooled ThermoCath Microwave Catheter:

	Default coolant setting temperature
Targis Microwave Catheter	8°C
CTC Advance and Cooled ThermoCath Microwave Catheters	15°C

The coolant temperature will ramp to its coolant setting temperature during a treatment. Press the **Close** button when done.

d) Press the **Ramp Rate** button: Press the up and down arrows to select the ramp rate: slow, medium, fast. Press the **Close** button when done.

Figure 3-36. Example of a treatment parameter control panel

3. Exit manual treatment mode by pressing the **Standard** button or the **Advanced** button from the Control Panel. The Control Unit will return to the automatic treatment mode.

3.3.5.4 Pausing a treatment or ending a treatment early

1. Press the **Pause/End** button from the Control Panel to pause the treatment and turn OFF microwave power.
2. Press the **Resume** button to resume treatment (Figure 3-37). To end treatment and go to cooldown, proceed to step 3.

Figure 3-37. Resume Treatment dialog box

3. Press the **Go To Cooldown** button (Figure 3-37). The cooldown 5-minute timer appears (Figure 3-38). This timer shows the time remaining until the end of cooldown, which also indicates how much time has passed since the microwave power was turned OFF (with the coolant pump still running).

Figure 3-38. Treatment Cooldown window

4. Select one of the following options in cooldown: remain in cooldown for the full 5 minutes, resume the treatment, or end the cooldown.

Notes:

- It is recommended that the cooldown phase last 5 minutes prior to exiting the treatment.
- Once you exit cooldown, the treatment is done and cannot be resumed.

a) Remain in cooldown: Cooldown ends after 5 minutes, and the Treatment Cooldown - End window appears (Figure 3-39). If you need to resume treatment, proceed to step 4b. Or, you can exit the treatment. Press the **Exit** button. A dialog box appears to confirm that you want to exit, and therefore end, this treatment.

Figure 3-39. Treatment Cooldown - End window

b) Resume the treatment: Press the **Resume Treatment** button (Figure 3-38) and then the **Resume** button (Figure 3-37) to resume the treatment.
c) End the cooldown: Press the **Cooldown End** button to end the cooldown (Figure 3-38). A dialog box appears to confirm that you want to end the cooldown, and therefore end, this treatment.

3.3.5.5 Ending a treatment

1. Monitor the cooldown 5-minute timer (Figure 3-30). This timer shows the time remaining until the end of cooldown, which also indicates how much time has passed since the microwave power was turned OFF (with the coolant pump still running).
2. Select one of the following options in cooldown: remain in cooldown for the full 5 minutes, reset the 5-minute cooldown timer, or end the cooldown.

Notes:

- It is recommended that the cooldown phase last 5 minutes prior to exiting the treatment.
- Once you exit cooldown, the treatment is done and cannot be resumed.

a) Remain in cooldown: Cooldown ends after 5 minutes, and the Treatment Cooldown - End window appears (Figure 3-40). If you need to reset the 5-minute cooldown timer, proceed to step 2b. Or, you can return to the Urologix® - BPH Treatment screen (Status Panel - status at pause). Press the **Resume Treatment** button (Figure 3-40). Finally, you can exit the treatment. Press the Exit button (Figure 3-40). A dialog box appears to confirm that you want to exit and therefore end this treatment.

Figure 3-40. Treatment Cooldown - End window

b) Reset the timer: Press the **Resume Treatment** button (Figure 3-38) and then the **Resume** button (Figure 3-37) to reset the 5-minute cooldown timer.
c) End the cooldown: Press the **Cooldown End** button to end the cooldown (Figure 3-38). A dialog box appears to confirm that you want to end the cooldown and therefore end this treatment.

3.4 Post-treatment

This section includes the steps to follow after completing a treatment: what to do with the CoolWave® Control Unit and associated devices and instructions for the patient post-treatment.

3.4.1 CoolWave Control Unit

Caution: Verify that the disposable components are removed intact.

1. Disconnect the coolant bag from the microwave catheter. To prevent water from draining out of the coolant bag and onto the floor, connect the Coolant Bag connectors to each other.
2. Disconnect the microwave catheter from the CoolWave Control Unit.
3. Remove all water from the microwave catheter location balloon, and withdraw the catheter from the patient.
4. Disconnect the rectal unit from the patient connection cable.
5. Remove all air from the rectal unit, and withdraw the device from the patient. If desired, pull the sheath of the RTU Plus up over the balloon to contain contaminants.
6. Remove the coolant bag from the CoolWave Control Unit.
7. Dispose of the single-use microwave catheter, single-use rectal unit or component, and the coolant bag in accordance with Universal Precautions for Contamination. Refer to *Section 4.1.1, Cleaning the RTU Plus Reusable Handle Post-Treatment*, for instruction on cleaning and disinfecting the RTU Plus Reusable Handle.
8. Print the treatment report or copy it to a Universal Serial Bus (USB) flash drive. Refer to *Section 3.5.3, Data View/Print/Copy screen*, for further information. Or, if you do not wish to print the treatment report or copy it to a USB flash drive, and no more treatments are scheduled for the day, turn the Control Unit OFF by pressing the ON/OFF power switch, located on the back of the unit ("0"). Hang the patient connection cable on the cable holder located on the back of the Control Unit. Cover the connectors at the end of the patient connection cable.
9. Follow these instructions if there are no other treatments in the near future: Disconnect the CoolWave Control Unit electrical cord from the wall outlet. Roll the CoolWave Control Unit to a storage location.

3.4.2 Patient

Due to edema from the thermal damage caused during treatment, the patient's prostate may swell and obstruct the urethra for a short period of time. For patient comfort, the physician may recommend the following treatment:

1. Instruct the patient in how to self-perform Clean Intermittent Catheterization, as needed, at home. If the patient fails a voiding trial after treatment, the physician may place a Foley catheter in the urethra before discharging the patient. The catheter may be removed within 24 to 60 hours or as the physician directs.
2. Instruct the patient, at discharge, to take prophylactic oral antibiotics for 3 days.
3. Provide the patient with sedatives, pain relievers, or anti-inflammatory medication as necessary.

3.5 Control Unit options

The Options Menu screen lists the following CoolWave Control Unit options: users, printer, data, password, and system (Figure 3-41). These options allow you to access printer utilities, copy a treatment report to a USB flash drive, print a treatment report, modify a password, or adjust system settings. And if you have administrative privileges, you will also have access to user settings. If you do not have administrative privileges, you will not see the **Users** button on the Options Menu screen.

Demonstration mode

When in demonstration mode, you will not have access to user settings. Therefore, you will not see the **Users** button on the Options Menu screen.

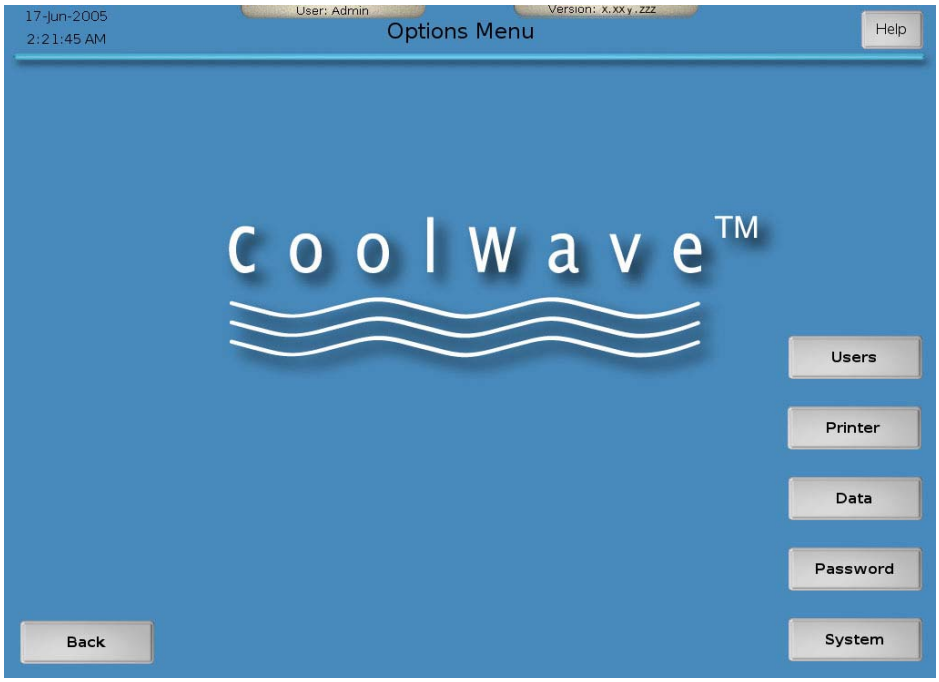


Figure 3-41. Options Menu screen

1. Press the **Users** button to view the User Settings screen. Refer to *Section 3.5.1, User Settings screen*, for further information.
2. Press the **Printer** button to view the Printer Utilities screen. Refer to *Section 3.5.2, Printer Utilities screen*, for further information.
3. Press the **Data** button to view the Data View/Print/Copy screen. Refer to *Section 3.5.3, Data View/Print/Copy screen*, for further information.
4. Press the **Password** button to view the Password Setup window. Refer to *Section 3.5.4, Password Setup window*, for further information.
5. Press the **System** button to view System Settings screen. Refer to *Section 3.5.5, System Settings screen*, for further information.
6. Press the **Back** button to return to the Main Menu screen. Refer to *Section 3.2.3, Main Menu Screen*, for further information.

3.5.1 User Settings screen

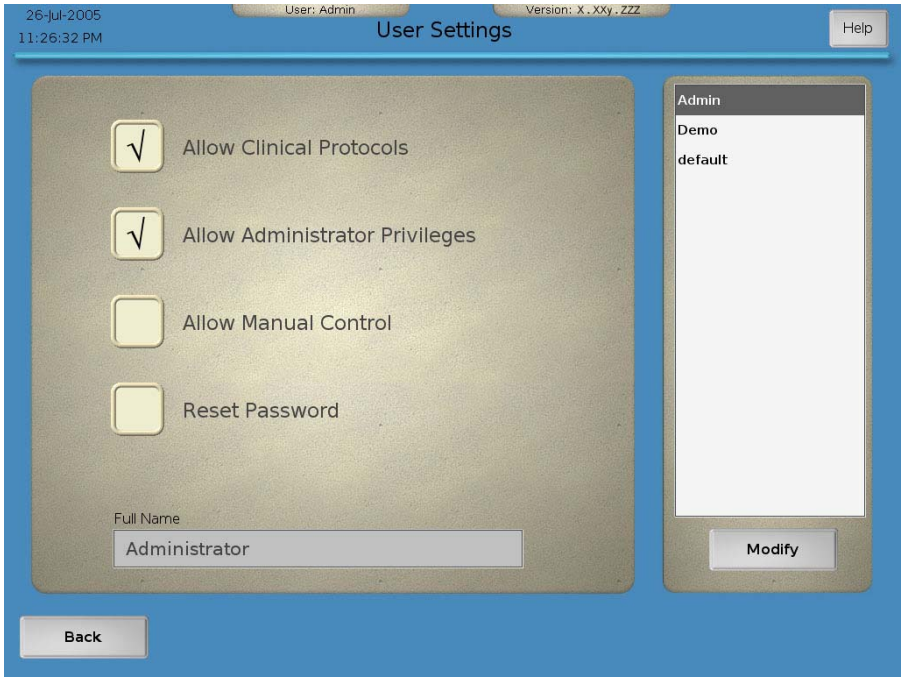


Figure 3-42. User Settings screen

1. Select a user from the menu on the right side of the screen, and press on the user name (Figure 3-42). That person's name appears in the Full Name data field on the bottom of the screen.
2. Press the **Modify** button.

   Note: The **Modify** button toggles between the **Modify** button and the **Apply** button.
3. Select the user setting(s) you want to change: Allow Clinical Protocols, Allow Administrator Privileges, Allow Manual Control, or Reset Password. Then, press the associated button.
   a) Press the **Allow Clinical Protocols** button: Provide or remove access to the clinical protocols for the selected user. If the button has a checkmark, remove access by pressing on the button. If the button does not have a checkmark, provide access by pressing on the button. Proceed to step 4.

      Note: Clinical protocols are not available unless provided by Urologix® for a Urologix-sponsored clinical study.

   b) Press the **Allow Administrator Privileges** button: Provide or remove administrator access (allows access to User Settings screen and all CoolWave® Control Unit data files) for the selected user; there is at least 1 site administrator per hospital or clinic. If the button has a checkmark, remove access by pressing on the button. If the button does not have a checkmark, provide access by pressing on the button. Proceed to step 4.
   c) Press the **Allow Manual Control** button: Provide or remove access to the manual treatment mode for the selected user. If the button has a checkmark, remove access by pressing on the button. If the button does not have a checkmark, provide access by pressing on the button. Proceed to step 4.

d) Press the **Reset Password** button: Activate or deactivate the password reset function for the selected user. If the button does not have a checkmark, reset the user's password to "password" by pressing on this button. If the button does have a checkmark, the password reset function is already active. Proceed to step 4.

4. Press the **Apply** button.
5. Press the **Back** button to return to the Options Menu screen.

3.5.2 Printer Utilities screen

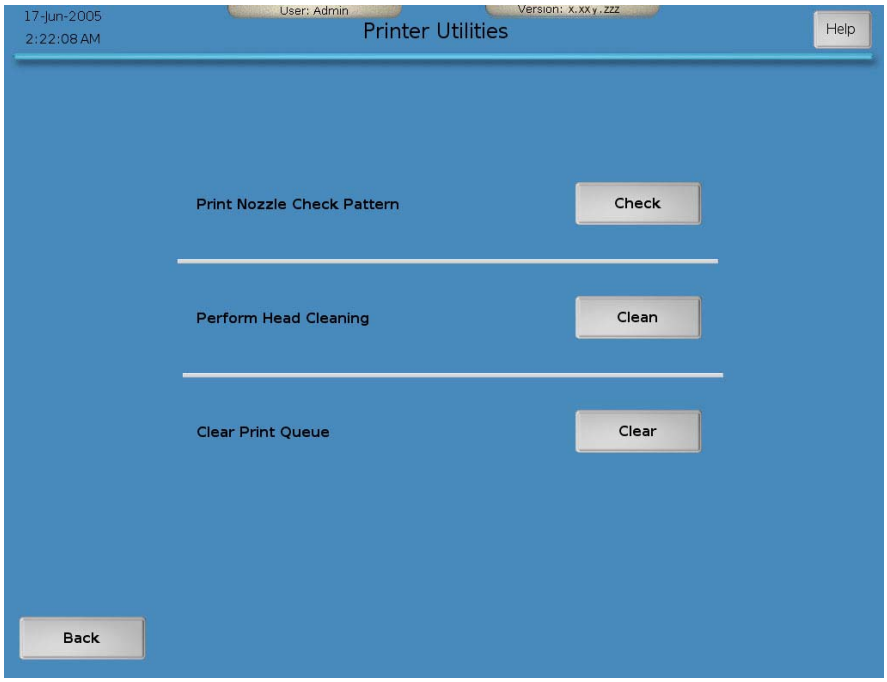


Figure 3-43. Printer Utilities screen

Note: Refer to *Section 4.3, Maintaining the printer*, Figure 4-3, for a printer overview.

1. Select one of the following printer utilities: Print Nozzle Check Pattern, Perform Head Cleaning, or Clear Print Queue (Figure 3-43).
   a) Print Nozzle Check Pattern: Determine if the ink is ejecting properly from the print head nozzles. A fuzzy printout means the print head needs cleaning. Turn the printer ON, load paper into the printer, and press the **Check** button. (However, if you pressed the **Check** button and paper was not in the printer, the printer flashes 1 long green and 2 short orange lights. Insert paper into the printer, and press the Resume/Cancel button on the printer.) The printer prints a nozzle check pattern.

Note: You can also print the nozzle check pattern from the printer. Refer to *Section 4.3.3, Printing the nozzle check pattern*, for further information.

   b) Perform Head Cleaning: A fuzzy printout means the print head needs cleaning. Clean the print head. Press the **Clean** button. The printer cleans the print head.

Notes:

- Print and inspect the nozzle check pattern before cleaning the print head: A print head cleaning uses up ink and should be performed only when needed.
- You can also clean the print head from the printer. Refer to *Section 4.3.4, Cleaning the Print Head*, for further information.

c) Clear Print Queue: Clear all print jobs from the printer memory. Press the **Clear** button. The printer clears the print queue.

2. Press the **Back** button to return to the Options Menu screen.

3.5.3 Data View/Print/Copy screen

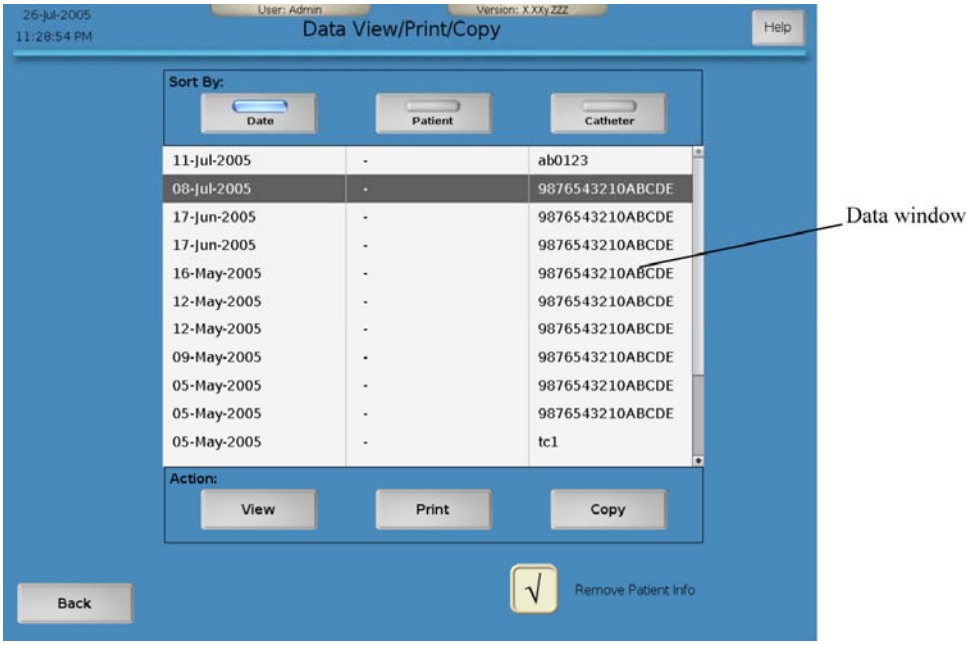


Figure 3-44. Data View/Print/Copy screen

1. Press the **Date**, **Patient**, or **Catheter** button to sort treatments by date (recent date first), by patient (alphabetical by last name - letter A first), or by microwave catheter serial number (lowest number first) (Figure 3-44). Unless you have administrative privileges, you can only access those treatment files you created: You cannot access treatment files created by other users.
2. Select a treatment in the Data window by pressing on the date, patient, or microwave catheter serial number. Then, press the **Remove Patient Info** button (optional) before choosing an action (view, print, or copy) to remove a patient's name from the treatment report: A check mark appears in the button.
   a) View: Press the **View** button to view a treatment report that includes patient data, treatment protocol data, treatment data, a treatment chart, the event log, and case notes. Use the arrows to scroll through the summary. Press the **Close** button to return to the Data View/Print/Copy screen.

b) Print: Turn the printer ON, load paper into the printer, and then press the **Print** button. (However, if you pressed the **Print** button and paper was not in the printer, the printer flashes 1 long green and 2 short orange lights. Insert paper into the printer, and press the Resume/Cancel button on the printer. Press the **Print** button again.) The printer prints the treatment report.

c) Copy: Insert a USB flash drive into the USB port. Press the **Copy** button to copy a treatment report to the drive. (However, if you pressed the **Copy** button before inserting the flash drive into the USB port, a dialog box appears instructing you to insert the drive. Insert the drive, close the dialog box, and press the **Copy** button again.) A dialog box appears to confirm that copying is in progress.

3. Press the **Back** button to return to the Options Menu screen.

3.5.4 Password Setup window

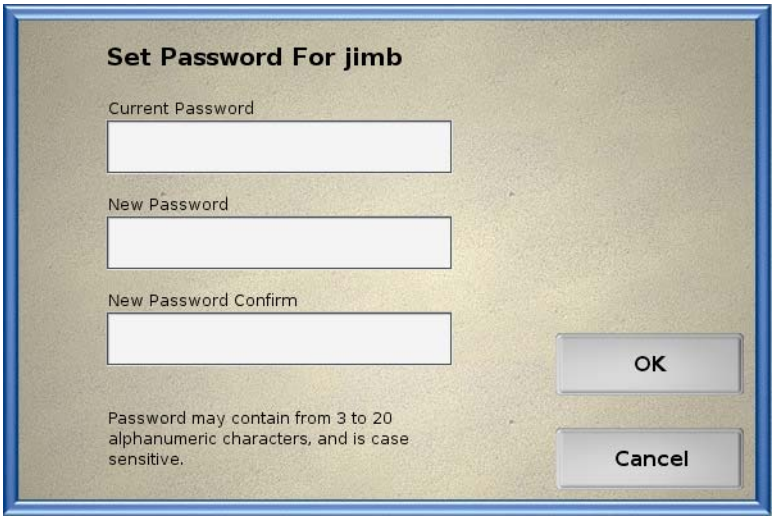


Figure 3-45. Password Setup window

1. Enter the following information in the Password Setup window: Current Password, New Password, and New Password Confirm (Figure 3-45). Your password, which is case sensitive, may contain from 3 to 20 alphanumeric characters.
2. Press the **OK** button to complete password setup. Or, press the **Cancel** button to leave the Password Setup window without changing the password.

3.5.5 System Settings screen

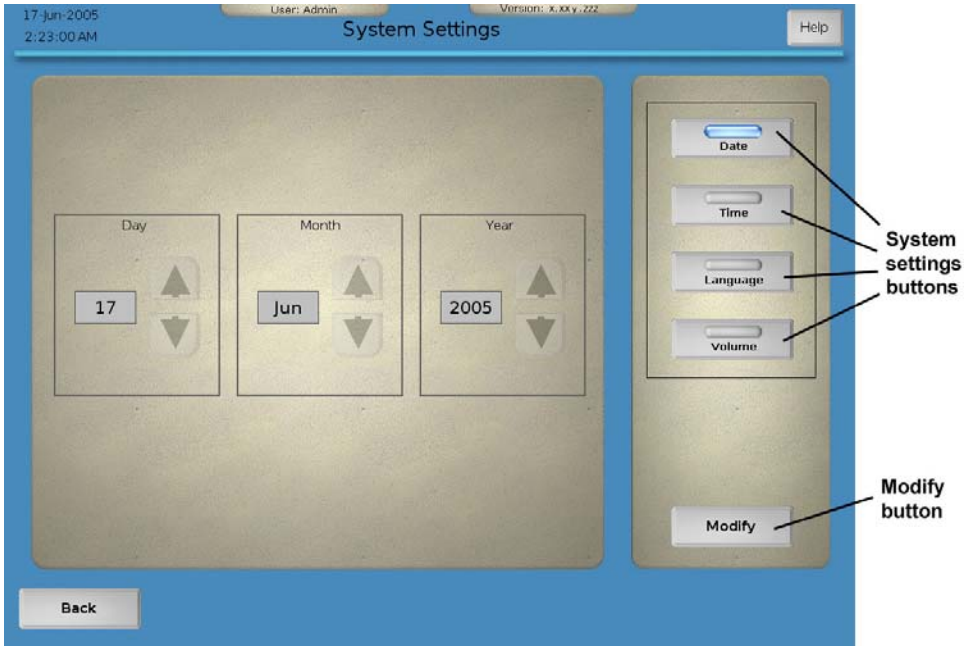


Figure 3-46. Example of a System Settings screen

1. Select the system setting to change: **Date**, **Time**, **Language**, or **Volume**. Then, press the associated button (Figure 3-46).
2. Press the **Modify** button (Figure 3-46). Refer to one of the following instructions based on the selected system setting.

   Note: The **Modify** button toggles between the **Modify** button and the **Apply** button.

   a) Date: Change the day, month, and year by pressing on the up and down arrows (Figure 3-47). Proceed to step 3.

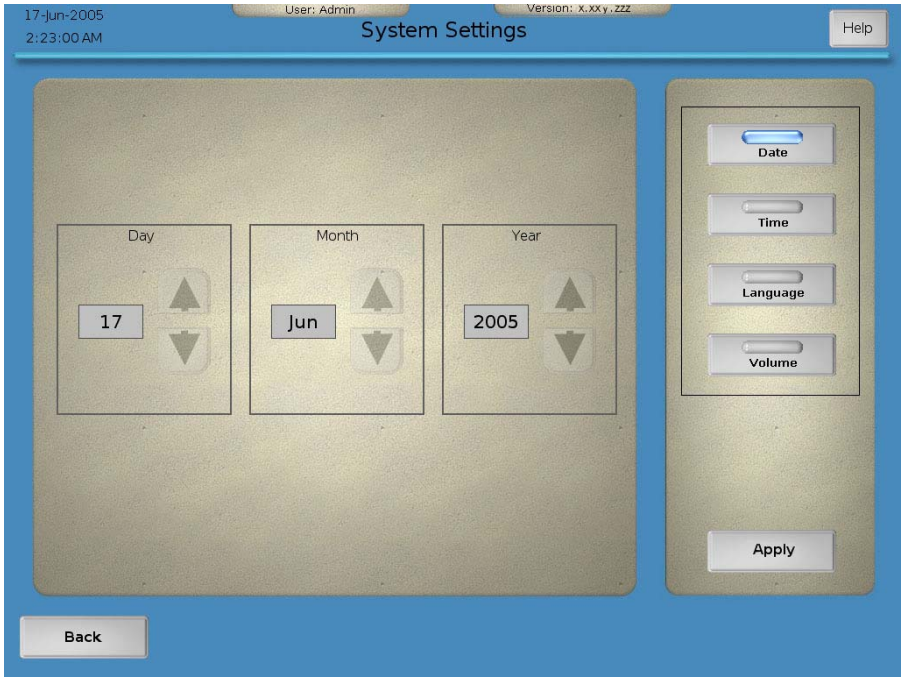


Figure 3-47. System Settings screen—date

b) Time: Change the hours, minutes, and AM/PM by pressing on the up and down arrows (Figure 3-48). Proceed to step 3.

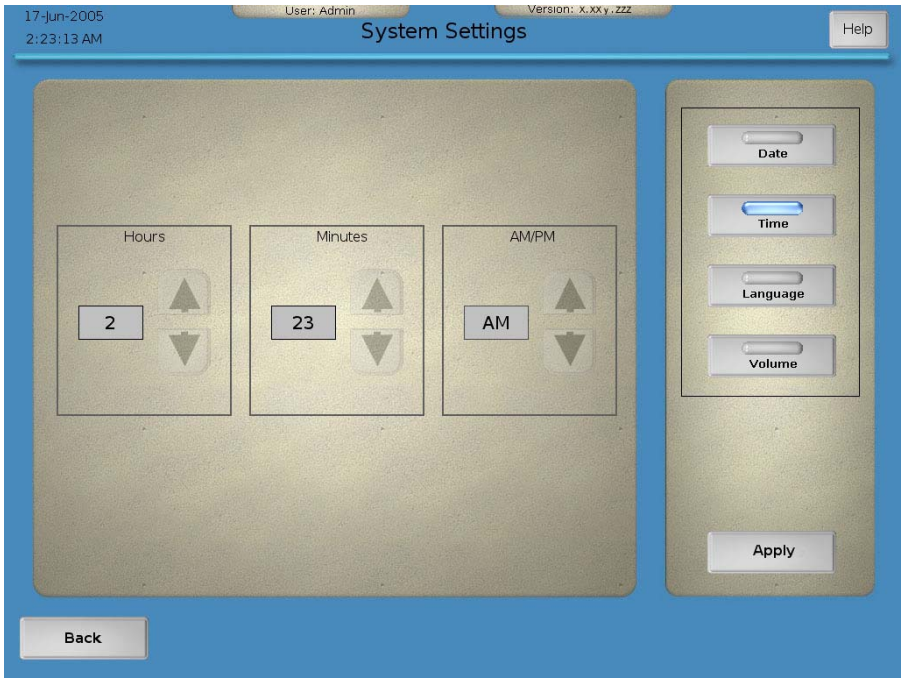


Figure 3-48. System Settings screen—time

c) Language: Change the language by pressing on the desired language (Figure 3-49). Proceed to step 3.

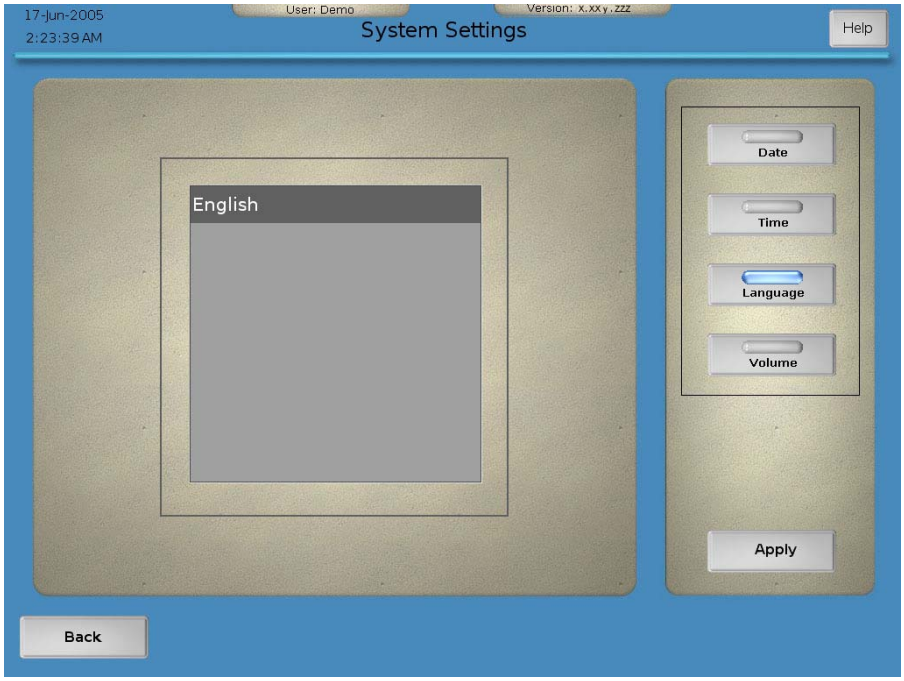


Figure 3-49. System Settings screen—language

d) Volume: Change the speaker volume by pressing on the bar and sliding it left (softer) or right (louder) (Figure 3-50). Proceed to step 3.

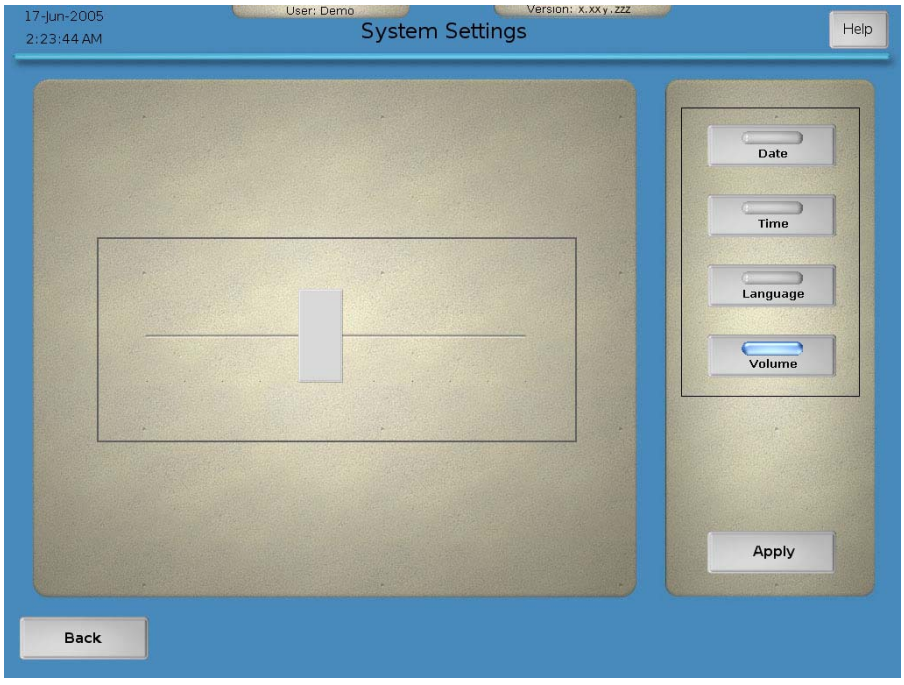


Figure 3-50. System Settings screen—volume

3. Press the **Apply** button to save the new system setting(s) (Figure 3-51).

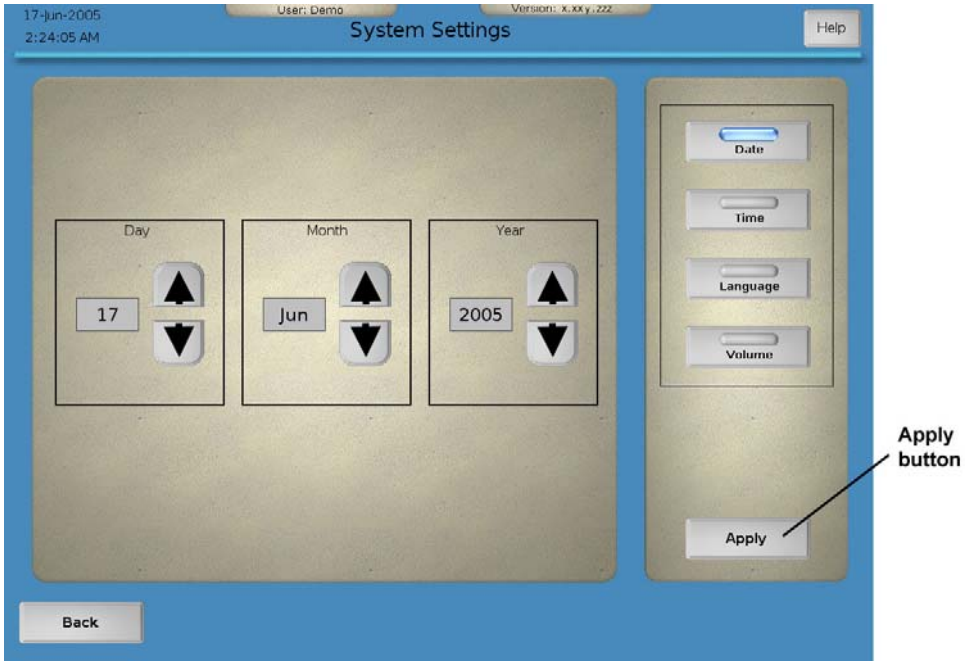


Figure 3-51. Example of a System Settings screen—apply

4. Press the **Back** button to return to the Options Menu screen.

3.6 System errors

This section contains information on system errors: general halt errors, calibration errors, and treatment errors. Error messages can appear on the System Error screen, the System Calibration screen, the Event pane, and the Detail pane.

Note: If you receive an error message on the System Calibration screen, the System Error screen, or while on the Urologix® - BPH Treatment screen, pressing the **Help** button provides you with information about the displayed error message.

3.6.1 General halt errors

If the CoolWave® Control Unit discovers a significant hardware problem, you will hear a single beep and an error message will appear on the System Error screen (Figure 3-52), in the Detail pane, or in the Event pane. You cannot continue using the CoolWave Control Unit: The **Reset** button (Event and Detail panes and System Error screen) and the **Resume Treatment** button (Cooldown pane) will appear grayed out. Review the following conditions and actions:

- Microwave power will turn OFF if there is a treatment in progress.
- The error message will be saved to the event log.
- The keyboard will no longer function.
- Run the CoolWave® Control Unit for 5 minutes to cool the patient's urethra before removing the microwave catheter, if applicable.
- Contact Urologix® Customer Service at 1-888-229-0772 for assistance.

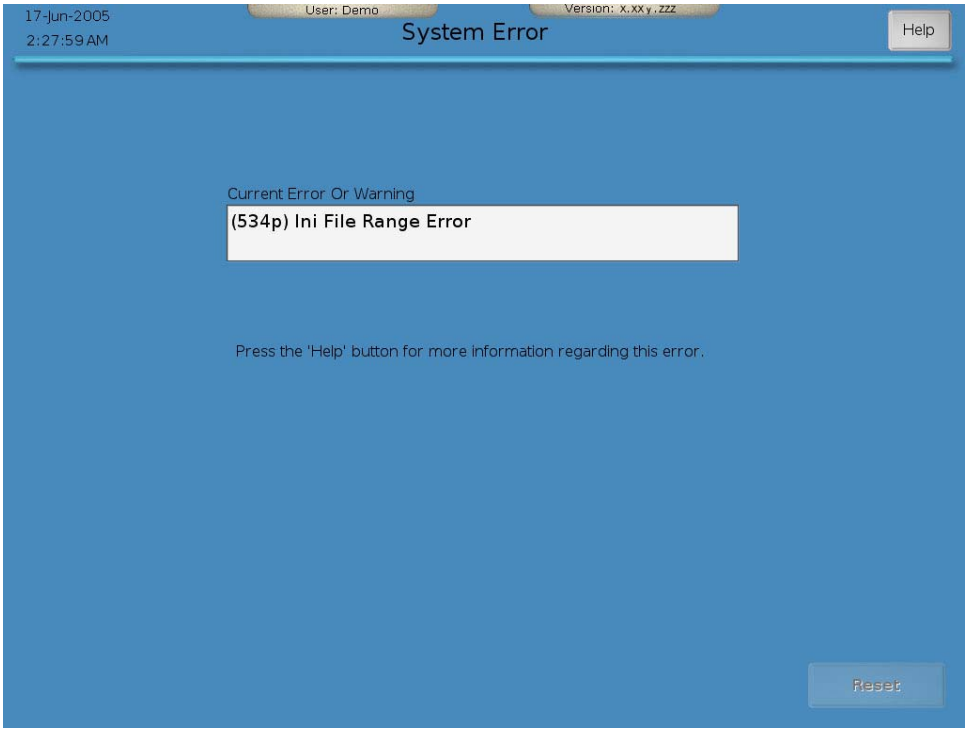


Figure 3-52. Example of a System Error screen - error message

3.6.2 Calibration errors

If an error occurs during the Control Unit calibration process, you will hear a single beep and an error message will appear on the System Error screen or the System Calibration screen. Review the following conditions:

- Microwave power will turn OFF if there is a calibration in progress.
- The error message will be saved to the event log.
- The keyboard will no longer function.

First, determine if the error message is on the System Error screen or the System Calibration screen (Figure 3-53). Error messages on the System Error screen indicate a system or patient critical error. You cannot continue using the CoolWave Control Unit: The **Reset** button will appear grayed out. Contact Urologix Customer Service at 1-888-229-0772 for assistance.

However, if the error message appears on the System Calibration screen, you will need to correct the problem. In most cases, an error message appears because the CoolWave® Control Unit failed to read or detect the microwave catheter temperature sensor, the rectal unit temperature sensors, the microwave catheter antenna connection, or the coolant bag pressure during the calibration process.

Normally, to correct the problem, you can readjust the appropriate connector to the device. Then, press the **Retry** button to restart the calibration process. Ultimately, you should use the error message to resolve any error condition. You can also refer to the actions listed on the System Calibration screen to help you determine what to do next.

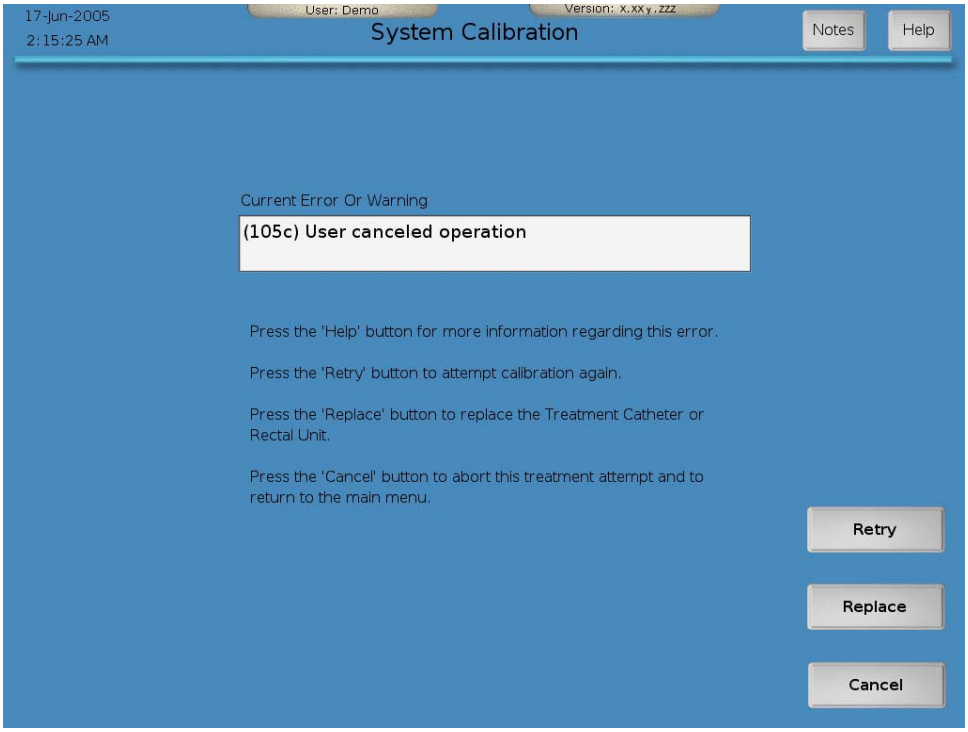

17-Jun-2005
2:15:25 AM
User: Demo
Version: x.xxy.zzz
System Calibration
Notes
Help
Current Error Or Warning
(105c) User canceled operation
Press the 'Help' button for more information regarding this error.
Press the 'Retry' button to attempt calibration again.
Press the 'Replace' button to replace the Treatment Catheter or Rectal Unit.
Press the 'Cancel' button to abort this treatment attempt and to return to the main menu.
Retry
Replace
Cancel

Figure 3-53. Example of a System Calibration screen - error message

Notes:

- If a calibration error message appears, refer to *Section 5.1, Troubleshooting guide*, for further information.
- Before replacing a microwave catheter or rectal unit, contact Urologix® Customer Service at 1-888-229-0772.

- Press the **Help** button: Learn more about the error message and the appropriate response.
- Press the **Retry** button: Proceed with CoolWave® Control Unit calibration. Refer to *Section 3.3.5, Urologix® - BPH Treatment screen*, for further information.
- Press the **Replace** button: Replace the microwave catheter or the rectal unit, as needed. Refer to *Section 2.6, Inserting the microwave catheter*, *Section 2.7, Inserting the Single-Use Standard RTU,* or *Section 2.8, Inserting the RTU Plus Reusable Handle and Single-Use Balloon*, for further information. The CoolWave Control Unit returns you to the Protocol screen. Refer to *Section 3.3.2, Protocol screen*, for further information.
- Press the **Cancel** button: Exit this treatment, and return to the Main Menu screen. Refer to *Section 3.2.3, Main Menu Screen*, for further information.

3.6.3 Treatment errors

If an error occurs during the treatment, you will hear a single beep and an error message will appear on the System Error screen, in the Event pane, or in the Detail pane. Some errors will not allow you to continue using the CoolWave Control Unit: The **Reset** button (Event and Detail panes and System Error screen) and the **Resume Treatment** button (Cooldown pane) will appear grayed out. However, some errors can be corrected: You will notice that the **Reset** button is not grayed out. Use the error message in the Event pane to correct the error. Then, press the **Reset** button to resume treatment. Review the following conditions and actions:

- Microwave power will turn OFF if there is a treatment in progress.
- The error message will be saved to the event log.
- The keyboard will no longer function (applies to errors on the System Error screen only).
- Run the CoolWave Control Unit for 5 minutes to cool the patient's urethra before removing the microwave catheter, if applicable.
- Contact Urologix® Customer Service at 1-888-229-0772 for assistance.

Note: If one of these messages appears, refer to *Section 5.1, Troubleshooting guide*, for further information.

3.7 Treatment modes

After completing the calibration process, the CoolWave Control Unit will enter the automatic treatment mode. The other treatment mode, available from the Urologix - BPH Treatment screen, is the manual treatment mode. This section provides background information on both of these treatment modes. However, for specific information on using the CoolWave Control Unit, begin with *Section 3.3,Cooled ThermoTherapy*™

3.7.1 Automatic treatment mode

In automatic treatment mode, the CoolWave® Control Unit automatically ramps the urethra and coolant temperatures to their settings based on the selected ramp rate. In addition, a CoolWave Control Unit operating in automatic treatment mode will adjust the coolant temperature to respond to rectal and urethra temperatures and will discontinue microwave power when the treatment timer has elapsed, therefore automatically beginning cooldown. The automatic treatment mode consists of 3 parts: ramp, treatment, and cooldown.

Note: If an error occurs during automatic treatment mode, the CoolWave Control Unit will turn OFF microwave power.

3.7.1.1 Ramp

- Monitor the patient for discomfort, and adjust the ramp rate, if necessary, from the advanced mode on the Control Panel.
- Adjust the microwave catheter and coolant setting temperatures as desired. However, Urologix® recommends using the default microwave catheter and default coolant setting temperatures.

3.7.1.2 Treatment

The treatment timer counts up the amount of time elapsed when the criteria defined in Table 3-4, *Section 3.3.5, Urologix® - BPH Treatment screen*, are met. If the rectal unit temperature is nearing 41°C, the CoolWave Control Unit automatically increases the temperature of the coolant (but not the displayed setting temperature) to compensate.

Adjust the treatment time to select when the automatic treatment mode automatically stops microwave power.

Note: The treatment timer runs when the following conditions occur:

Targis® Short & Standard	CTC Advance® Short	CTC Advance® Cooled ThermoCath® Standard & Long
• Urethra ≥ **35** ℃, with (Urethra - Coolant) difference ≥ **23** ℃ • OR: MW Power ≥ **50** W • OR: RTU ≥ **41** ℃	• Urethra ≥ **35** ℃, with (Urethra - Coolant) difference ≥ **20** ℃ • OR: MW Power ≥ **50** W • OR: RTU ≥ **41** ℃	• Urethra ≥ **35** ℃, with (Urethra - Coolant) difference ≥ **20** ℃ • OR: MW Power ≥ **65** W • OR: RTU ≥ **41** ℃

Monitor the patient for discomfort, and adjust the following settings, if necessary:

- Decrease the urethra setting temperature from the standard mode or the advanced mode on the Control Panel.
- Increase the coolant setting temperature from the advanced mode on the Control Panel.

Read all error messages and respond accordingly. If possible, clear the error message by pressing the **Reset** button. After the message clears, the Control Unit resumes the treatment in the automatic treatment mode.

After the treatment time expires, cooldown will automatically start, and the Treatment Cooldown window will appear.

3.7.1.3 Cooldown

The cooldown 5-minute timer shows the time remaining until the end of cooldown, which also indicates how much time has passed since the microwave power was turned OFF (with the coolant pump still running).When the 5-minute cooldown period ends, the coolant pump will continue running with the cooldown timer at 00:00. Coolant will continue circulating until you end the treatment.

- Resume the treatment, remain in cooldown, or end the cooldown (exit treatment), if desired, from the Treatment Cooldown window.
- Remain in cooldown, reset the 5-minute cooldown timer, or end the cooldown (exit treatment) when the Treatment Cooldown - End window appears.

3.7.2 Manual treatment mode

In manual treatment mode, you can adjust the microwave power, the coolant pump status (ON vs. OFF), the coolant setting, and the ramp rate; the physician defines the treatment time. And in manual treatment mode, the CoolWave Control Unit will continue to deliver microwave power until the physician ends the treatment. The manual treatment mode consists of 3 parts: ramp, treatment, and cooldown.

Notes:

- If you do not have access to the manual treatment mode, you will not see this option on the Control Panel.
- When the automatic treatment mode is turned ON from the manual treatment mode, the CoolWave® Control Unit will ensure that the treatment time is increased to have at least 2 minutes of treatment remaining, unless doing so exceeds the treatment time setting temperature. The CoolWave Control Unit will also return to the previous urethra setting temperature.

3.7.2.1 Ramp

1. Verify that the coolant temperature is at the default setting, and wait until the measured coolant temperature has reached ≤ the default setting +4°C before applying microwave power.
2. Use the **Power Setting** button to apply 20 W of microwave power. Wait 2 minutes. Use the interval timer as a guide for timing additional power adjustments.
3. Continue to increase microwave power by 5 W, at 2 minute intervals, until:
   - The microwave catheter ≥ 35°C (the treatment timer will begin automatically, since the conditions for it to run should have been met), or
   - The rectal unit reaches 40°C, or
   - The patient is experiencing discomfort.
4. Increase microwave power by 1 W per minute, once 1 of the 3 conditions in step 3 are met, until:
   - The microwave catheter reaches 40°C +/-1°C, or
   - The rectal unit ≥ 41.5°C, or
   - Microwave power reaches 60 W for a Targis® or CTC Advance® Short Microwave Catheters or 75 W for a Cooled ThermoCath® or CTC Advance® Standard & Long Microwave Catheters
   - The patient is experiencing discomfort.

3.7.2.2 Treatment

Throughout the treatment, carefully monitor the patient's comfort level and the microwave catheter and rectal unit temperatures.

Note: The treatment timer runs when the following conditions occur:

Targis® Short & Standard	CTC Advance® Short	CTC Advance® Cooled ThermoCath® Standard & Long
• Urethra ≥ **35**°C, with (Urethra - Coolant) difference ≥ **23**°C • OR: MW Power ≥ **50** W • OR: RTU ≥ **41**°C	• Urethra ≥ **35**°C, with (Urethra - Coolant) difference ≥ **20**°C • OR: MW Power ≥ **50** W • OR: RTU ≥ **41**°C	• Urethra ≥ **35**°C, with (Urethra - Coolant) difference ≥ **20**°C • OR: MW Power ≥ **65** W • OR: RTU ≥ **41**°C

Maintain the optimum microwave catheter temperature of 40°C +/-1°C.

Monitor the patient for discomfort, and adjust the following settings, if necessary:

- Decrease the urethra setting temperature by decreasing the microwave power from the manual mode on the Control Panel.
- Increase the coolant setting temperature from the manual mode on the Control Panel.

Decrease microwave power, if the rectal unit exceeds 42°C, in 1 W per minute increments until the rectal unit is 41.5°C. If the rectal unit temperature does not respond as quickly as needed, decrease power by 3 W increments. When the rectal unit temperature begins to decrease, try to increase microwave power to achieve and maintain the microwave catheter at 40°C +/-1°C while maintaining rectal temperatures at or below 42°C.

After at least 28 minutes and 30 seconds of treatment, end the treatment by pressing the **Pause/End** button from the Control Panel and go to cooldown. The Treatment Cooldown window will appear.

3.7.2.3 Cooldown

The cooldown 5-minute timer shows the time remaining until the end of cooldown, which also indicates how much time has passed since the microwave power was turned OFF (with the coolant pump still running).When the 5-minute cooldown period ends, the coolant pump will continue running with the cooldown timer at 00:00. Coolant will continue circulating until you end the treatment.

- Resume the treatment, remain in cooldown, or end the cooldown (exit treatment), if desired, from the Treatment Cooldown window.
- Remain in cooldown, reset the 5-minute cooldown timer, or end the cooldown (exit treatment) when the Treatment Cooldown - End window appears.

4 Equipment Maintenance

4.1 Cleaning the equipment

4.1.1 Cleaning the RTU Plus Reusable Handle Post-Treatment

The following process can be used to clean and disinfect the RTU Plus Reusable Handle (containing the temperature sensors) for subsequent use. The RTU (rectal unit) handle should not be used more than 30 times.

1. Remove and discard the disposable rectal balloon if not already discarded.
2. It is recommended that a glove be tied over the rectal unit cable connector to prevent it from being splashed or soaked.
3. Rinse the rectal unit handle with warm running tap water until all or most visible gross debris is removed. Avoid any water contact with the connector. Gently shake to remove excess water and to avoid splashing or casting of solution.
4. Place the rectal unit handle in a bath with water and enzymatic detergent (e.g., ENZOL®) mixture diluted according to the manufacturer's instructions (typically 1 oz ENZOL per gallon of water) for 2 minutes. **Do not soak or immerse the connector**. After soaking 2 minutes, clean the crevices with a soft bristle brush. Pay special attention to the temperature sensor "flex circuit" bend points, sensor/handle junction, and inflation tubing channel to avoid damage and to ensure adequate cleaning.
5. Rinse the rectal unit handle for 2 minutes using warm tap water. Gently shake to remove excess water and to avoid splashing or casting of solution.
6. Inspect the rectal unit handle under standard lighting to verify that all soil was removed. If not, repeat above steps.
7. Rinse the rectal unit handle with deionized water to remove any excess residues left by the tap water. Gently shake to remove excess water and to avoid splashing or casting of solution.
8. Soak the rectal unit handle (again, **do not soak or immerse the connector**) in CIDEX PLUS® according to the manufacturer's instructions for high-level disinfection (typically 20 minutes at 20°C -25°C).
9. After soaking, rinse devices per manufacturer's instructions (typically 3 separate 1-minute soaks in copious volumes of deionized water).
10. Gently dry the rectal unit handle. Store in dry, ambient conditions between 59°F -95°F (15°C - 35°C) until the next use. Always avoid bending the temperature sensor strip significantly.

4.1.2 Cleaning the Control Unit

There are no special clean-up operations required after a Cooled ThermoTherapy™ Treatment for the CoolWave Control Unit. The CoolWave Control Unit exterior should be cleaned periodically following these instructions:

- Clean the exterior surface of the CoolWave® Control Unit with a soft, lint-free cloth dampened with warm water and a diluted detergent, 10% dilution of bleach, or a diluted, nonabrasive, nonstaining standard hospital disinfectant. Use a lint-free cloth dampened with warm water to rinse the surface of the unit.
- Do NOT use isopropyl alcohol (IPA) to wipe the exterior CoolWave Control Unit housing. Using cleaning solvents such as IPA could result in damage to the CoolWave Control Unit.

4.1.3 Cleaning the touchscreen

The touchscreen should be cleaned periodically following these instructions:

- Clean the touchscreen with a soft, lint-free cloth dampened with a solution of 50% IPA and 50% warm water. Or, use 100% IPA instead of the IPA and water solution.
- Do NOT spray the cleaning solution directly on the screen. The solution may seep inside the display or stain the bezel.

4.2 Maintaining the CoolWave® Control Unit

If a product failure occurs, the defective device must be returned to Urologix® for evaluation and reimbursement.

4.2.1 Daily Maintenance

Before using the CoolWave Control Unit, you should visually inspect system components for damage. Refer to *Section 1.8.1, Installation*, for a list of the system components requiring inspection.

- Wipe the exterior surface of the CoolWave Control Unit with a 10% solution of bleach or mild detergent. Wipe the exterior surface of the unit with water to rinse.
- Keep the touchscreen clean. If the screen needs cleaning, refer to *Section 4.1.3, Cleaning the touchscreen,* for further information.
- Check the printer paper. If the printer needs a paper refill, refer to *Section 4.3.1, Refilling the printer with paper*, for further information.
- Check all cables and power connections. Be certain that all cables are firmly attached and routed away from normal traffic paths.
- Check the sight gauge on the rear of the CoolWave Control Unit to ensure that the internal coolant level is within the white open section of the correct level indicator (Figure 4-1).

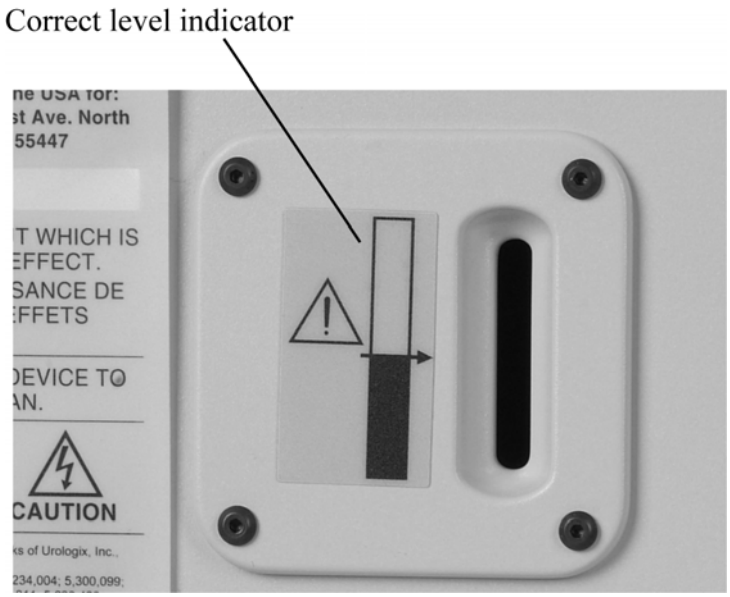


Figure 4-1. Internal coolant level indicator

4.2.2 Periodic maintenance

Equipment service and yearly preventive maintenance must be performed by a Urologix® trained and authorized service representative. Contact Urologix Customer Service (1-888-229-0772) if more than 12 months have passed since the last preventive maintenance. Refer to Additional **Terms and Conditions, Exhibit A**, packaged with the CoolWave® Control Unit, for equipment warranty information. Please note: An extended service agreement is available through Urologix. Contact your Urologix sales representative for further information. Any other type of service or maintenance arrangement will void all warranties and claims.

4.2.3 Replacing the fuses

1. Use a flat screwdriver to remove the fuse holder caps (Figure 4-2).

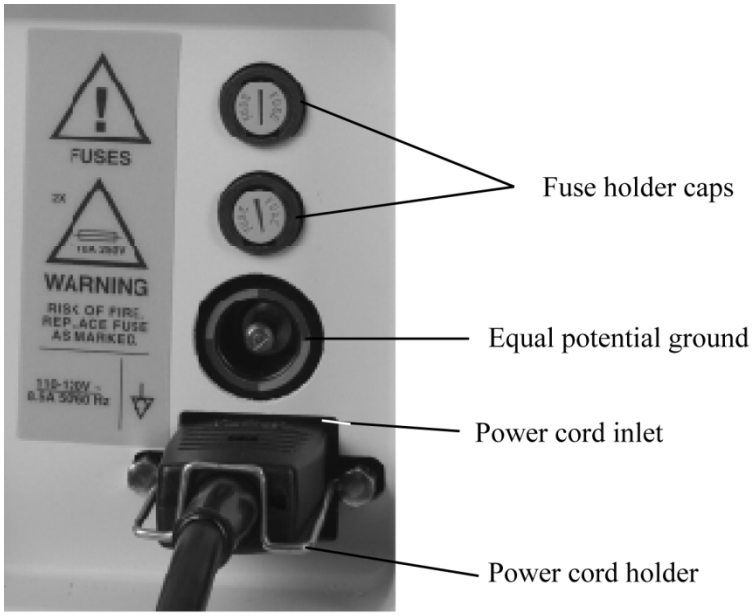


Figure 4-2. Control Unit rear cover

2. Replace the defective fuses with the appropriate Urologix fuses listed below.

Control Unit Model	Fuse Catalog Number	Fuse Type/Rating
Model 5000A	AC1008	1 1/4" x 1/4" / 10 A
Model 5000E	AC1009	5 mm x 20 mm / 5 A

Table 4-1. Fuse overview

Warning: Only replace CoolWave Control Unit fuses with Urologix® supplied components.

3. Replace the fuse holder caps.

4.3 Maintaining the printer

Printer maintenance consists of refilling the printer with paper, replacing an ink tank, printing the nozzle check pattern, and cleaning the print head. Refer to the instructions below as well as the technical manual that comes with your Canon® color inkjet printer.

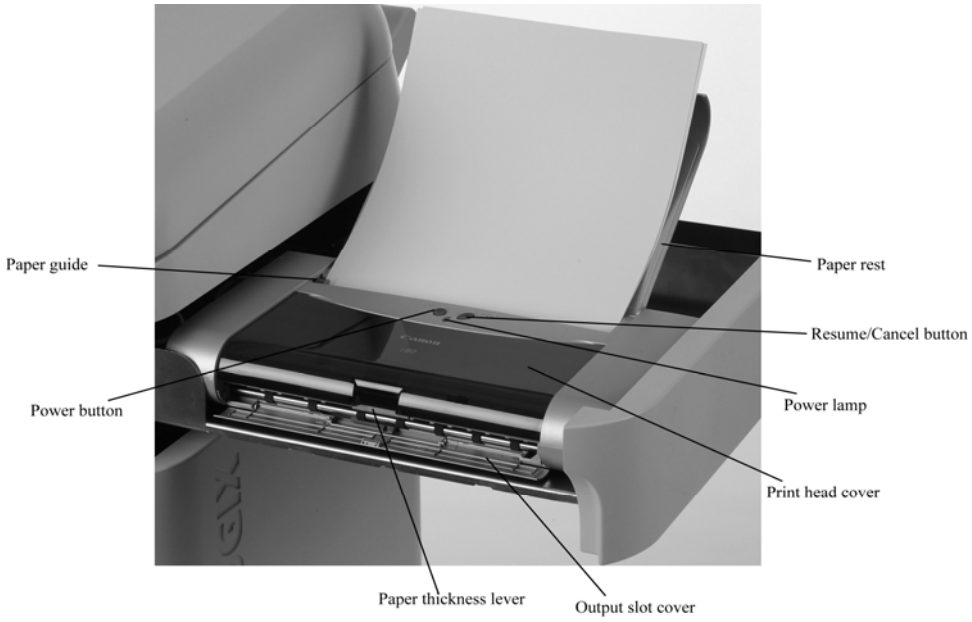


Figure 4-3. Printer overview

4.3.1 Refilling the printer with paper

Notes:

- Do not load more than 10 sheets of paper in the output slot cover.
- Avoid touching a printed sheet until the ink dries.

1. Make sure the paper is flat and not curled at the edges.
2. Open the paper rest and output slot cover (Figure 4-3).
3. Slide the paper thickness lever (Figure 4-3) to the right position.
4. Insert the paper into the sheet feeder while aligning it against the right side of the feeder.
5. Position the paper guide (Figure 4-3) against the left side of the paper.

4.3.2 Replacing an Ink Tank

Notes:

- Replace an empty ink tank immediately. Printing with an empty ink tank may cause problems with the printer.
- Check the model number on the new ink tank to make sure you are using the correct one.
- Be careful not to stain your clothing or other items while replacing an ink tank.
- Dispose of an empty ink tank according to local laws and regulations regarding disposal of consumables.
- Use an ink tank within the first 6 months after it is installed.
- Do not remove an ink tank, leave it out in the open, and then place that ink tank back into the printer. The ink in the ink tank will have dried out and may cause the printer to malfunction.

1. Open the paper rest, and press the Power button (Figure 4-3). The power lamp, next to the Power button, will be green when the printer is ready (Figure 4-3).

2. Open the print head cover (Figure 4-3).
3. Push the tab on the old ink tank, and remove the tank.
4. Remove the new ink tank from its package, and remove the orange protective cap.

Notes:

- Do not replace the orange protective cap after removing it from the new ink tank.
- Do not touch the open ink port after removing the orange protective cap.

5. Insert the new ink tank, with it slightly slanted, into the ink tank slot (Figure 4-4).

Figure 4-4. Insert the new ink tank

6. Push down on the PUSH symbol on the ink tank until it clicks into place.
7. Close the print head cover. The print head will move to the right.

4.3.3 Printing the nozzle check pattern

Note: You can also print the nozzle check pattern from the Printer Utilities screen. Refer to *Section 3.5.2, Printer Utilities screen*, for further information.

1. Open the paper rest, and press the Power button (Figure 4-3). The power lamp, next to the Power button, will be green when the printer is ready (Figure 4-3).
2. Load paper into the printer.
3. Press and hold the Resume/Cancel button (Figure 4-3) on the printer. When the power lamp flashes twice, the printer prints the nozzle check pattern.
4. Inspect the nozzle check pattern printout. Missing lines in the chart mean the print head for the black ink cartridge needs cleaning. White stripes in the bar graph mean the print head for the

color ink cartridge needs cleaning. Refer to *Section 4.3.4, Cleaning the Print Head*, for further information.

Note: If the nozzle check pattern does not print properly, and the ink level is low, replace the ink tank. Refer to *Section 4.3.2, Replacing an Ink Tank*, for further information.

4.3.4 Cleaning the Print Head

Notes:

- Print and inspect the nozzle check pattern before cleaning the print head: A print head cleaning uses up ink and should be performed only when needed.
- You can also clean the print head from the Printer Utilities screen. Refer to *Section 3.5.2, Printer Utilities screen*, for further information.

1. Open the paper rest, and press the Power button (Figure 4-3). The power lamp, next to the Power button, will be green when the printer is ready (Figure 4-3).
2. Press and hold the Resume/Cancel button (Figure 4-3) on the printer. When the power lamp flashes once, the printer cleans the print head.

4.4 Moving the CoolWave® Control Unit

When moving the CoolWave Control Unit, grip the handle at the top of the unit. This handle is designed to allow one person to push or pull the unit with little effort.

The wheels of the unit pivot to assist you when turning the unit in a new direction. The front wheels have an individual lock you can use when the unit is stationary. To lock the wheels, use your foot to press down on the wheel lock tabs. To unlock the wheels, press on the back part of the wheel lock tab.

Several safeguards or cautions apply when moving the CoolWave Control Unit.

Protect the patient connection cable when moving the CoolWave Control Unit. Although a cable holder is provided on the rear of the CoolWave Control Unit for the patient connection cable, the cable is still susceptible to damage. Do not pull on or stress the cable.

- Always handle the touchscreen with care.
- Maintain the CoolWave Control Unit in an upright position when it is in use or being stored.
- Avoid tipping the unit. Since the CoolWave Control Unit is heavy, it will be damaged if it were to tip over. In addition, personal injury could result.
- Do not lift or elevate the CoolWave Control Unit.

4.5 Storing the CoolWave® Control Unit

For short and long-term storage, handle the CoolWave Control Unit as you would other sensitive medical equipment: Store the CoolWave Control Unit in a low-moisture equipment storage area where it may be kept long-term. Keep the surfaces and components of the CoolWave Control Unit free of dust by covering the unit with plastic.

4.6 Shipping the CoolWave® Control Unit

In the event that it becomes necessary to ship the CoolWave Control Unit, contact Urologix® Customer Service at 1-888-229-0772. For repeated transportation of the CoolWave Control Unit, Urologix offers a Transport Kit, which is the only FDA-approved method for transporting the CoolWave Control Unit.

4.7 CoolWave® Control Unit specifications

CoolWave Control Unit Models:	5000E (Europe) 5000A (US)
Power Requirements:	5000E: 220/240 V [+/- 10%] (4.25 A) Single phase 50 or 60 Hz 5000A: 110/120 V [+/- 10%] (8.5 A) Single phase 50 or 60 Hz
Microwave Output:	Power: 0 W-75 W output from the microwave antenna connector on the patient cable, continuous duty Frequency: 902 MHz to 928 MHz
Coolant Circulation System:	Chill Element: Thermoelectric Capacity: 100 W element Configuration: Disposable Coolant Bag Bag Dimensions: Approximately 15.2 cm x 17.8 cm Bag Capacity: Approximately 100 mL Pump: Peristaltic pump
User Interface:	Display: Color liquid crystal display or LCD Input: Touchscreen Keyboard: Silicone rubber keyboard
Operating Conditions:	Temperature: +10°C to +30°C Humidity: 30% to 75% relative humidity Atmospheric Pressure: 700 hPa to 1,060 hPa
Shipping / Storage Conditions:	Temperature: -20°C to 70°C Humidity: 10% to 95% relative humidity Atmospheric Pressure: 700 hPa to 1,060 hPa
Class/Type:	IEC 60601-1 Class I, Type BF with defibrillation protection
Measurements Range and Accuracy:	Rectal Sensor: Range 1°C-50°C, Accuracy 1°C from 35°C to 45°C and 2°C outside this range Urethra Sensor: Range 27°C-47°C, Accuracy ±1°C Coolant Temperature: Range -25°C-75°C, Accuracy ±3°C Microwave Power: Range 0 W-75 W, Accuracy ±10%
FCC Registration	#0012913901

Table 4-2. CoolWave Control Unit specifications

5 Appendix

5.1 Troubleshooting guide

Each system error has a unique number, and may be followed by a single letter suffix that indicates where the error occurred. For example, 000x is a system error where "000" is the system error number, and the "x" is the single letter suffix. See the following table for the letter suffix definitions:

X	Where the system error occurred
blank	during treatment
a	calibration—temperature stabilization
b	calibration—rectal sensor
c	calibration—fiber optic sensor
d	calibration— coolant pump
e	calibration—frequency sweep
p	prior to treatment

Below is a list of system errors (in numerical order), possible causes, and the actions to take to resolve the error (s). If you still cannot resolve an error after using this troubleshooting guide, please contact Urologix® Customer Service at 1-888-229-0772.

Error #1 - Rectal Temp. High

Possible Causes	Action Steps
1. Loose connector.	Reattach connector.
2. Temperature in rectum has exceeded 42.5°C.	Allow rectal temperature to drop below 42°C.
3. Enema not performed within 2 hours of treatment.	Remove rectal unit and perform enema.
4. Air may not have been removed from the original volume (cc's) in the rectal unit.	Remove air per Section 2.7 or 2.8.
5. Rectal unit may not be inserted properly.	Check that the rectal unit is properly positioned.
6. Patient improperly positioned.	Reposition patient with head and shoulders elevated no higher than a 20° angle.
7. Microwave catheter may not be positioned properly.	Check that the microwave catheter is properly positioned.
8. Rectal unit may be defective.	Replace rectal unit.

Error #2 - Rectal Temp. Low

Possible Causes	Action Steps
1. Loose connector.	Reattach connector.
2. Rectal unit temperature below 31°C.	Check that the rectal unit is inserted properly.
3. Rectal unit expelled or not properly inflated.	Reinsert the rectal unit, or inflate the rectal unit.
4. Rectal unit may not be inserted properly.	Check that the rectal unit is properly positioned.
5. Rectal unit may be defective.	Replace the rectal unit.

Error #3 - Coolant Press. High

Possible Causes	Action Steps
1. Pressure too high in tubing.	Check that the pump tubing clamp is properly fastened, and that the tubing is not kinked.
2. Coolant bag may be defective.	Disconnect coolant luers from the microwave catheter, temporarily connect coolant luers to each other, and then restart treatment. If error repeats, replace coolant bag. Otherwise, check the microwave catheter.
3. Microwave catheter may be defective.	Disconnect coolant luers from microwave catheter and flush microwave catheter coolant luers with sterile water. Reconnect coolant bag luers to microwave catheter and restart treatment. If error repeats, replace microwave catheter.

Error #4 - Coolant Press. Low

Possible Causes	Action Steps
1. Pressure is too low in the tubing.	Check water level in the coolant bag. Check that pump tubing clamp is properly fastened.
2. Coolant tubing between coolant bag and sensor module may be twisted.	Verify tubing is not twisted.
3. Coolant bag may be defective.	Replace the coolant bag.
4. Microwave catheter may be defective.	Replace the microwave catheter.

Error #5 - Urethra Temp. High

Possible Causes	Action Steps
1. Loose microwave catheter fiber connector.	Reattach fiber connector. Clean both ends of connection with alcohol wipe or swab.
2. Temperature in urethra > 44.5°C	Allow microwave catheter temperature to drop ≤ 41°C.
3. Microwave catheter may be defective.	Replace the microwave catheter.

Error #6 - Urethra Temp. Low

Possible Causes	Action Steps
1. Loose microwave catheter fiber connectors.	Reattach fiber connector. Clean both ends of connection with alcohol wipe or swab.
2. Microwave catheter may be defective.	Replace the microwave catheter.

Error #7 - Catheter Efficiency Low

Possible Causes	Action Steps
1. Cable may not be connected properly.	Reattach connector.
2. Urine drainage line not purged.	Purge urine drainage line.
3. Microwave catheter may not be inserted properly.	Check that the microwave catheter is inserted properly.
4. Defective microwave catheter.	Replace the microwave catheter, and recalibrate.

Error #8 - Control Unit Temp. High

Possible Causes	Action Steps
1. CoolWave® Control Unit vents blocked.	Remove any item blocking vents.
2. Treatment room too warm.	Observe CoolWave Control Unit operating temperature requirements.

Error #11 - Coolant Temp. High

Possible Causes	Action Steps
1. Coolant door open.	Close coolant door.
2. Coolant temperature > 40°C.	Reduce coolant set point to the proper temperature, and wait for coolant to drop below 40°C.
3. Coolant Bag may be defective.	Replace the Coolant Bag.

Error #12 - Coolant Temp. Low

Possible Causes	Action Steps
1. Coolant door open.	Close coolant door.
2. Coolant bag may be defective.	Replace the coolant bag.

Error #13 - Rectal Temp. High

Possible Causes	Action Steps
1. Loose connector.	Reattach connector.
2. Temperature in rectum has exceeded 42.5°C.	Allow rectal temperature to drop below 42°C.
3. Enema not performed within 2 hours of treatment.	Remove the rectal unit, and perform enema.
4. Air may not have been removed from the original volume (cc's) in the rectal unit.	Remove air per Section 2.7 or 2.8.
5. Rectal unit may not be inserted properly.	Check that the rectal unit is properly positioned.
6. Patient improperly positioned.	Reposition patient with head and shoulders elevated no higher than a 20° angle.
7. Microwave catheter may not be positioned properly.	Check that the microwave catheter is properly positioned.
8. Rectal unit may be defective.	Replace the rectal unit.

Error #14 - Rectal Temp. Low

Possible Causes	Action Steps
1. Loose connector.	Reattach connector.
Rectal unit temperature below 15°C.	Check that the rectal unit is inserted properly.
2. Rectal unit expelled or not properly inflated.	Reinsert the rectal unit, or inflate the rectal unit.
3. Rectal unit may not be inserted properly.	Check that the rectal unit is properly positioned.
4. Rectal unit may be defective.	Replace the rectal unit.

Error #15 - Coolant Press. High

Possible Causes	Action Steps
1. Pressure too high in tubing.	Check that pump tubing clamp is properly fastened, and that the tubing is not kinked.
2. Coolant bag may be defective.	Disconnect coolant luers from microwave catheter, temporarily connect the coolant luers to each other, and then restart treatment. If error repeats, replace coolant bag. Otherwise, check the microwave catheter.
3. Microwave catheter may be defective.	Disconnect coolant luers from the microwave catheter and flush microwave catheter coolant luers with sterile water. Reconnect coolant bag luers to the microwave catheter, and restart treatment. If error repeats, replace the microwave catheter.

Error #16 - Coolant Press. Low

Possible Causes	Action Steps
1. Pressure is too low in the tubing.	Check water level in the coolant bag. Check that the pump tubing clamp is properly fastened.
2. Coolant tubing between coolant bag and sensor module may be twisted.	Verify tubing is not twisted.
3. Coolant bag may be defective.	Replace the coolant bag.
4. Microwave catheter may be defective.	Replace the microwave catheter.

Error #17 - Urethra Temp. High

Possible Causes	Action Steps
1. Loose microwave catheter fiber connector.	Reattach fiber connector. Clean both ends of connection with alcohol wipe or swab.
2. Temperature in urethra > 44.5°C.	Allow microwave catheter temperature to drop ≤ 41°C.
3. Microwave catheter may be defective.	Replace the microwave catheter.

Error #18 - Urethra Temp. Low

Possible Causes	Action Steps
1. Loose microwave catheter fiber connectors.	Reattach connector.
2. Microwave catheter may be defective.	Replace the microwave catheter.

Error #19 - Catheter Efficiency Low

Possible Causes	Action Steps
1. Cable may not be connected properly.	Reattach connector.
2. Microwave catheter may not be inserted properly.	Check that the microwave catheter is inserted properly.
3. Urine drainage line not purged.	Purge urine drainage line.
4. Defective microwave catheter.	Replace the microwave catheter, and recalibrate.

Error #20 - Pump Latch Open

Possible Causes	Action Steps
1. Coolant pump clamp latch is open.	Close the latch.
2. Lift lever has failed.	Open and close lift lever, and listen for 2 clicks.

Error #21 - User Pressed "Microwave Off"

Possible Causes	Action Steps
1. User accidentally pressed the Microwave Off pushbutton.	Press the **Resume** button or the **Reset** button to continue.
2. Patient was experiencing pain.	Resume treatment after the pain level has reduced.
3. Microwave indicator was illuminated when it should not have been.	Call Urologix Customer Service.

Error #22 - Rectal Unit Disconnected

Possible Causes	Action Steps
1. Rectal unit has become disconnected.	Reattach the rectal unit to the patient connection cable housing.

Error #23 - Urethra Signal Weak

Possible Causes	Action Steps
1. Loose microwave catheter fiber connectors.	Reattach connector.
2. Microwave catheter may be defective.	Replace the microwave catheter.
3. Patient cable may be defective.	Call Urologix Customer Service.

Error #50 - Maximum Treatment Time Exceeded

Possible Causes	Action Steps
1. Treatment timer has exceeded 60 minutes.	Press the **Pause/End** button to begin cooldown.

Error #51 - Maximum MWG Time Exceeded

Possible Causes	Action Steps
1. 100 minutes have elapsed since completing calibration.	Press the **Pause/End** button to begin cooldown.

Error #52 - Warning: Urethra Temp. >41°C

Possible Causes	Action Steps
1. Urethra temperature is too high.	Reduce microwave power to maintain urethra temperature below 41°C.

Error #99 - Urethra Temp Probe Error

Possible Causes	Action Steps
1. Loose microwave catheter fiber connectors.	Reattach connector.
2. Microwave catheter may be defective.	Replace the microwave catheter.

Error #100 - Rectal Unit Cal. Failure

Possible Causes	Action Steps
1. All 5 rectal sensors are not within required temperature range.	Allow time for temperatures to stabilize, and press the **Retry** button. If unsuccessful, replace the rectal unit.
2. Rectal unit not properly inserted or inflated.	Ensure that the rectal unit is inserted and inflated properly. Then, press the **Retry** button.
3. Defective rectal unit.	Replace the rectal unit.

Error #101 - Urethra Temp Cal Fail

Possible Causes	Action Steps
1. Fiber optic connector may be improperly connected.	Disconnect and reconnect microwave catheter fiber optic connector to patient connection cable housing.
2. Fiber optic connector may be dirty.	Disconnect fiber optic connector, inspect for foreign material, and clean with isopropyl alcohol and swab.
3. Microwave catheter may not be properly inserted.	Ensure that the microwave catheter is properly inserted in patient.
4. Microwave catheter may be defective.	Replace the microwave catheter.
5. Patient cable may be defective.	Call Urologix® Customer Service.

Error #103 - MW Calibration Failure

Possible Causes	Action Steps
1. Antenna connector may be improperly connected.	Reattach the connector, being careful not to cross-thread it.

2. The urine drainage lumen may contain air.	Purge the urine drainage lumen with fluid.
3. Microwave catheter may be defective.	Replace the microwave catheter.

Error #105 - User canceled operation

Possible Causes	Action Steps
1. Calibration stopped by user.	Address reason for stopping calibration, and resume calibration sequence.

Error #198 - Invalid Catheter Type Detected

Possible Causes	Action Steps
1. Microwave catheter type in RFID does not match.	Replace the microwave catheter.

Error #199 - Urethra Temp. Cross-Check.

Possible Causes	Action Steps
1. Internal voltage fluctuation relating to fiber optic sensor.	Press the **Retry** button if available.

ERROR #300 - Control Unit Temp. Too High

Possible Causes	Action Steps
1. CoolWave® Control Unit vents are blocked on the sides or back of the machine.	Remove any item that may be blocking the vents.
2. CoolWave Control Unit internal temperature > 60°C.	Allow the CoolWave Control Unit to continue pumping coolant through the catheter. Call Urologix® Customer Service.

ERROR #317 - Low Voltage Startup

Possible Causes	Action Steps
1. Low voltage at start-up.	Verify that an extension cord is not being used, and check the circuit breaker for sufficient current capability.
2. Hardware failsafe switch in wrong position.	Call Urologix Customer Service.

ERROR #423 - Different Rectal RFID

Possible Causes	Action Steps
1. The rectal unit RFID tag is different from the one displayed on the Protocol Screen.	Reattach the original rectal unit and select the **Retry** button, or select the **Replace** button to return to the Protocol Screen using the currently attached rectal unit.

ERROR #424 - Invalid Tag

Possible Causes	Action Steps
1. An RFID tag is being read, but it contains invalid data.	Remove the connectors from both disposable devices, and replace them individually. Observe the rectal unit and microwave catheter serial number fields to determine which RFID tag is invalid.

ERROR #425 - Different Catheter RFID

Possible Causes	Action Steps
1. The catheter RFID tag is different from the one displayed on the Protocol Screen.	Reattach the original microwave catheter and select the **Retry** button, or select the **Replace** button to return to the Protocol Screen using the currently attached catheter.

ERROR #426 - Multiple Catheter RFIDs

Possible Causes	Action Steps
1. More than 1 microwave catheter near the patient connection cable housing.	Remove the extra microwave catheters from the area around the patient cable.

ERROR #427 - Multiple Rectal RFIDs

Possible Causes	Action Steps
1. More than 1 rectal unit near the patient connection cable housing.	Remove the extra rectal units from the area around the patient cable.

ERROR #428 - No Catheter RFID Sensed

Possible Causes	Action Steps
1. The microwave catheter RFID tag has been removed from the patient connection cable housing area.	Replace the same microwave catheter so that the CoolWave® Control Unit can access the RFID tag.
2. The microwave catheter RFID tag is not in range.	Adjust the orientation of the tag label on the microwave catheter so that it can be read.

ERROR #429 - No Rectal RFID Sensed

Possible Causes	Action Steps
1. The rectal unit RFID tag has been removed from the patient connection cable housing area.	Replace the same rectal unit so that the CoolWave Control Unit can access the RFID tag.
2. The rectal unit tag is not in range.	Adjust the orientation of the tag label on the rectal unit so that it can be read.

ERROR #431 - Many RFIDs Sensed

Possible Causes	Action Steps
1. More than 4 RFID tags are near the patient connection cable housing.	Remove other microwave catheters and rectal units from the patient connection cable housing area.

CONTROL UNIT DOES NOT RECOGNIZE SERIAL NUMBER

Possible Causes	Action Steps
1. RFID Tag not in Antenna Field	Verify that serial tag is adjacent to

Connection cable housing	connector and rotated such that it touches the flat portion of the Patient Cable Connector
2. RFID field being affected by surrounding metallic surfaces	If Patient cable Connector is setting on a metallic surface, raise it off the surface by setting it on a nonmetallic spacer such as a towel.

Error# and Error Name - detected by software

309	Synthesizer Unlocked	466	Msg Queue Open Error
311	File Open Error	467	Msg Queue Not Open
312	Urethra Temp Comm Fail	468	Msg Queue Already Open
313	MW Comm. Failure	469	Msg Queue Create Error
314	Parameter Error	470	Process Internal Error
315	Watchdog Timeout	471	Process Start Error
316	Disk Free Error	472	Condvar Wait Error
322	File CRC Failure	473	Error Reading Safety Data
375	MW Software (Low)	510	Data Write Error
376	MW Software (High)	511	Data Read Error
377	MW Software (Mid)	512	Mutex Set Error
378	MW Software Reverse	513	Mutex Clear Error
379	MW Software Forward	514	Write Error
398	Memory Free Error	515	Read Error
399	Urethra Temp Setup Error	516	Seek Error
418	Urethra Temp. Failure	517	Language File Open Error
430	RFID Comm. Failure	518	Language Internal Error
442	File Missing	519	Language String Overflow
443	Msg Queue Filling Warning	520	Language Array Overflow
444	Memory Free Warning	521	Language Array Underflow
445	Disk Free Warning	522	Language Mgr Not Open
451	Software Watchdog Test Failure	523	Language Mgr Init Error
452	Msg Queue Overflow	524	Data Manager Not Open
453	Process Status Error	525	Data Manager Initialization
456	Resource Mgr Read Error	526	File Length Error
457	Mutex Unlock Error	527	File Size Error
458	Mutex Lock Error	529	Device Not Open
459	Mutex Init Error	530	Device Already Open
460	Timer Multiple Ticks Missed	531	Device Open Error
461	Data Corruption Error	532	Process Spawn Error
462	Msg Queue Receive	533	Scan Data Error
463	Msg Queue Send Error	534	Ini File Range Error
464	Msg Queue Destroy Error	535	Ini File Label Error
465	Msg Queue Open Error	536	Ini Section Error

Possible Causes	**Action Steps**
1. Detected in the software.	Allow coolant system to run for 5 minutes on the System Error screen. Reboot the CoolWave® Control Unit by turning it OFF. Wait until the fans stop, and then turn the unit ON again. If the error

Error# and Error Name - detected by software

	occurred during treatment, wait 15 minutes before restarting treatment. Note: The error may repeat again. Call Urologix® Customer Service to report the error.

Error# and Error Name - hardware failures

301	Coolant Hotside Low	308	Rectal Sensor Interface
302	Coolant Coldside Low	319	HWFS Disconnected
303	Hardware Failsafe Malfunction	320	MW Supply
304	HW Sensor Address Error	387	Coolant Coldside High
305	MW Interface	388	Coolant Hotside High
306	Internal Sensor	389	Control Unit Temp. Too Low
307	MW Hardware	449	HW Control Register Error

Possible Causes	**Action Steps**
1. Nonresolvable hardware failure.	Will probably need a field service visit to resolve the problem. Allow coolant system to run for 5 minutes on the System Error screen and call Urologix® Customer Service. Note: If the coolant pump is not running, manually irrigate.

5.2 Treatment screen flowchart

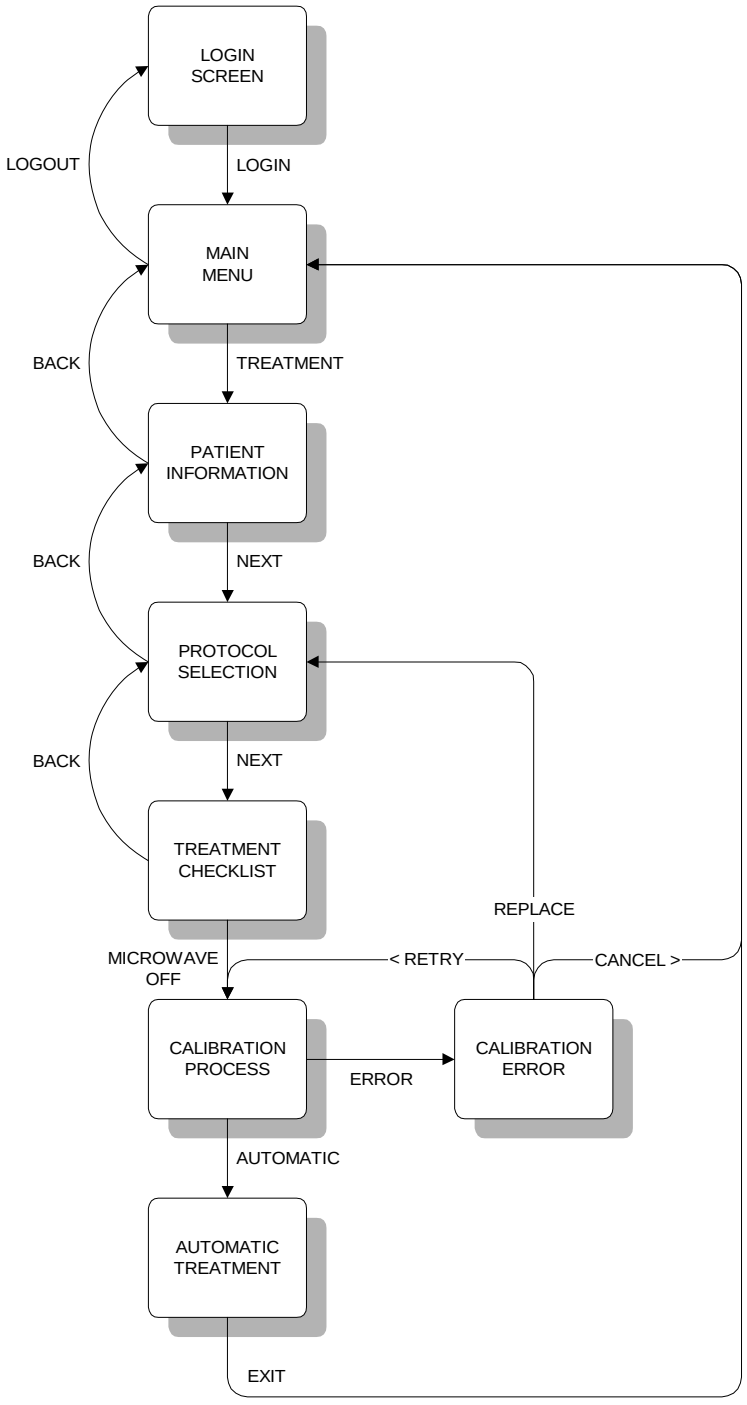
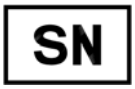
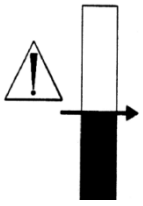
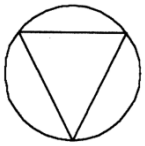
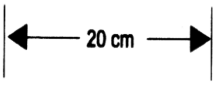
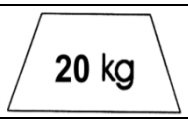


Figure 5-1. Treatment screen flowchart

5.3 Description of symbols

There are a number of symbols associated with the Targis® System CoolWave® Control Unit, Microwave Catheter, RTU and Coolant Bag. Some of these symbols appear in Section 1 of this manual. Other symbols Urologix® adopted from the international community to assist you in understanding Urologix labeling.

Symbol	Description
	Alternating current
	Catalog Number
	Batch Code / Lot Number
	Serial Number
	Do not re-use
	Equal potential ground
	Fuse type and value
	Internal reservoir level
	Nonionizing radiation (microwave power)
	Operate on a level surface

Symbol	Description
RTU	Rectal unit
	Consult Instructions for Use
	Caution
	Stop microwave energy
	Type BF equipment with defibrillation protection
	Sterilized Using Ethylene Oxide
	Use By Date
	Temperature Limitation
	Do Not Resterilize
	Recyclable Package
	Keep objects 20 cm from vents
	Do not place heavy objects on drawer

Symbol	Description
	Caution cold surface
	Do Not Use if Package is Damaged
	Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician trained and/or experienced in the use of this device as outlined in the required training program
	Note
	Caution
	Warning
	Date of Manufacture
	Manufacturer
	Authorized Representative in the European Community

Table 5-1. Description of symbols

5.4 Patient Comfort Kit

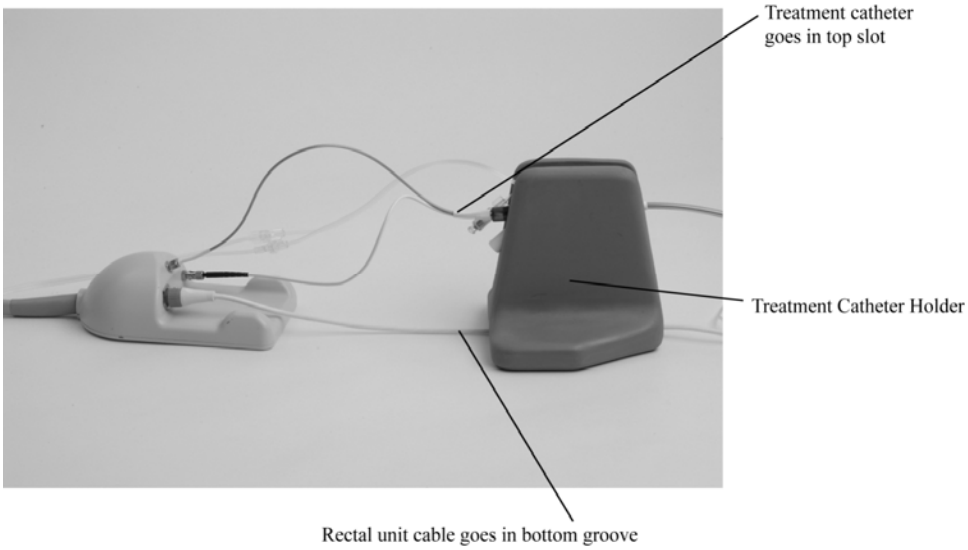


Figure 5-2. Microwave catheter Holder

Figure 5-3. Knee cushions

5.5 Glossary

Advanced mode
Select advanced mode from the Control Panel on the Urologix® - BPH Treatment screen to adjust treatment parameters (urethra setting, treatment time, coolant setting, and ramp rate) during a Cooled ThermoTherapy™ Treatment in automatic treatment mode.

Analgesia
The reduction of pain stimulus without the corresponding loss of consciousness.

Analgesic
A medication that reduces or eliminates pain. In BPH patients, depending on the clinician's diagnosis, there are several agents that might be considered for the reduction of pain.

Antibiotic
A substance that is used to destroy or inhibit the growth of microorganisms.

Anti-inflammatory
A medication that is used to reduce inflammation, which is often characterized by localized heat, redness, swelling, and pain in the tissues.

Automatic treatment mode
The CoolWave Control Unit begins a Cooled ThermoTherapy Treatment, based on the selected treatment protocol, and continues with that treatment until the end of cooldown, without the need for adjusting any treatment parameters.

Benign Prostatic Hyperplasia (BPH)
A nonmalignant but abnormal increase in the tissue of the prostate gland that sometimes results in constriction of the urethra.

BPH
The acronym for Benign Prostatic Hyperplasia.

Cable holder
Located on the back of the CoolWave Control Unit, the cable holder provides a place to store the power cord and the patient connection cable and housing.

Calibration process
A diagnostic test that the CoolWave Control Unit runs to determine whether its components are functioning properly: (1) Rectal unit and temperature sensors are operating within 2 degrees of each other; (2) Urethra temperature sensor is operational; (3) Pressure in the microwave cooling system is normal; and (4) Antenna is operational, as verified by a frequency sweep.

Catheterization
The placement of the microwave catheter or urine drainage catheter into the urethra.

Chill plate
One of the components of the CoolWave Control Unit coolant system that removes heat from the coolant bag.

Computer subsystem
The CoolWave® Control Unit contains a computer that allows the clinician to input patient identification data, control the treatment, and collect treatment data.

Control Panel
The area of the Urologix® - BPH Treatment screen that allows you to adjust urethra temperature, treatment time, coolant temperature, and ramp rate. You can also pause or end a treatment.

Coolant Bag
The coolant bag is comprised of 3 main subassemblies: coolant bag (coolant reservoir), sensor module, and tubing with connectors. The coolant bag is a container that fits against the chill plate. It is filled with sterile, distilled water (coolant) that circulates through the microwave catheter during treatment to preserve urethral tissue.

Coolant door
The large panel on the right side of the CoolWave® Control Unit behind which is located the coolant bag, chill plate, temperature sensor, pressure sensor, and peristaltic pump mechanism.

Coolant pump
See peristaltic pump mechanism.

Coolant set point
The temperature at which the cooling system is set to regulate the temperature of the water circulating through the microwave catheter. The actual water temperature may be different from this value during the time that the system chills or warms the water. Once the water reaches the coolant set point value, the coolant temperature is maintained within a small tolerance of this value.

Coolant system
The coolant system consists of a chill plate, temperature and pressure sensors, a peristaltic pump mechanism, and a coolant bag.

Coolant temperature
The actual measured temperature of the water circulating through the microwave catheter. This temperature is measured at the sensor block just before the water leaves the Control Unit.

Cooldown
The time in a treatment when the microwave power is OFF, the coolant pump is running, and the cooldown 5-minute timer appears.

Cooled ThermoCath® Microwave catheter
A type of microwave catheter.

Cooled ThermoTherapy™ Treatment
A medical procedure that uses microwave energy to destroy the prostatic tissue that constricts the urethra while preserving urethral function and tissue.

Cooling channel
The tiny passageways, adjacent to the antenna within the microwave catheter, that transport chilled, sterile water throughout the catheter to maintain a urethral temperature.

Cooling lumen
See cooling channel.

CTC Advance® Microwave Catheter
A type of microwave catheter.

Data field
An area on the touchscreen where you can enter information.

Demonstration mode
Demonstration mode simulates a Cooled ThermoTherapy Treatment and allows you to work with the CoolWave System as though you were performing a treatment on a patient.

Dialog box
A dialog box appears on the touchscreen and provides additional information or instruction during a treatment.

Ejaculation
The discharge of semen through the penis during sexual excitement.

Exclusion criteria
A list of conditions that may bar a prospective patient from participating in a BPH clinical trial.

Frequency sweep
An internal diagnostic test the CoolWave Control Unit performs to determine the functional status of the microwave antenna once it is placed inside the patient.

Gross hematuria
A profuse quantity of blood in the urine.

Help feature
Provides information on error messages and topics within the CoolWave System.

Hospital or clinic ID
The patient's medical record number.

Impotence
The inability to achieve an erection.

Incontinence
The inability to control urination.

Interval timer
The mechanism in the CoolWave® Control Unit that displays the time at which the last power adjustment occurred.

Location balloon
The inflatable portion of the microwave catheter found near the tip that locates the microwave antenna within the bladder/bladder neck.

Manual mode
Though the CoolWave Control Unit begins a treatment, based on the selected treatment protocol, you can manually adjust the microwave power and coolant pump (ON vs. OFF) during the treatment.

Messages
Directions or reports that assist the clinician in monitoring a Cooled ThermoTherapy™ procedure.

Microwave antenna
The CoolWave Control Unit component within the microwave catheter that generates heat energy to destroy prostate tissue.

Microwave Off pushbutton
The red button, located under the touchscreen on the CoolWave Control Unit, that allows you to discontinue the delivery of microwave power immediately.

Microwave catheter
A disposable, catheter-based devise (which is delivered sterile) that is inserted into the urethra. It includes a fiber optic temperature sensor to measure urethral temperature, a microwave antenna and cable, cooling channels and connectors, a urine drainage port that connects to a standard urine drainage bag, and a location balloon to position the catheter at the bladder neck.

Microwave catheter balloon
See location balloon.

Microwave Catheter Holder
The Microwave Catheter Holder is designed to hold the microwave catheter in position during treatment.

Microwave catheter serial number
The serial number of the microwave catheter used in a treatment and required for the patient’s data file.

MW
An abbreviation for microwave.

Neurogenic bladder
Dysfunctional urinary bladder caused by a lesion of the nervous system.

Notes feature
A place to enter a patient’s treatment information during a treatment.

Obstructive bladder neck syndrome
An impairment of the outlet area of the bladder caused by prostate tissue constricting the urethra.

Orientation flag
The vertical guide on the rectal unit, approximately 1" in height that serves the clinician in correctly positioning the rectal balloon.

Patient Comfort Kit
A CoolWave® Control Unit accessory which includes 2 knee cushions and Microwave Catheter Holder. It provides comfort for the patient and holds the catheter in position for the duration of treatment.

Patient connection cable
An extension cable that connects the patient connection cable housing to the CoolWave Control Unit.

Patient connection cable housing
The patient connection cable housing contains connectors for the rectal unit, fiber optic connector, and microwave connector.

Perineum
An anatomical landmark between the scrotum and the anus.

Peristaltic pump mechanism
The small, wheel-like motorized drive behind the coolant door of the CoolWave Control Unit that uses peristaltic action to propel coolant through the coolant inlet tubing to the microwave catheter and beyond. Also referred to as the coolant pump.

Power set point
Represents the actual microwave power output exactly equal to the power setting within the accuracy limits of the CoolWave Control Unit.

Preprostatic urethra
The proximal portion of the prostatic urethra. It runs through the prostate beginning just distal to the bladder neck and ending just proximal to the verumontanum.

Pressure sensor
The small metal disk that fits against the diaphragm of the sensor module on the lower right front side of the CoolWave Control Unit. Its function is to detect changes in pressure within the tubing of the microwave catheter and signal potential coolant leaks.

Procedure Kit
The Procedure Kit contains 1 disposable microwave catheter, 1 disposable rectal unit, and 1 coolant bag.

Prostate gland
A partly muscular, partly glandular organ that surrounds the neck of the bladder and the urethra. It secretes an alkaline viscose fluid that provides maintenance and activation of sperm at ejaculation.

Prostatic median lobe
The middle rounded mass of 3 rounded masses of tissue that develop adjacent to the urethra in the hyperplastic prostate.

Prostatism
Disease of the prostate gland.

Pump mechanism
See peristaltic pump mechanism.

Pump tubing clamp
The fastening arm just above the peristaltic pump mechanism that locks the coolant inlet tubing in place as it is routed out of the Control Unit console to the microwave catheter.

Rectal temperature
The temperature reported by the warmest of the 5 sensors in the rectal unit.

Rectal thermosensing unit (RTU)
A device with temperature sensors that monitors the patient's rectal temperatures when the device is positioned correctly within the rectum along the rectal prostatic wall. It is connected to the patient connection cable, via the patient connection cable housing, of the CoolWave® Control Unit.

Rectal unit serial number
The serial number of a rectal unit.

Rectum
The terminal portion of the intestine (continuation of the sigmoid colon) that ends in the anus.

Retrograde ejaculation
Sometimes called "dry climax," this event refers to the discharge of semen backwards into the bladder. The condition may result from surgery that cuts the muscle that blocks the entrance to the bladder.

RFID
An acronym for radio frequency identification.

RTD
An acronym for Resistive Thermal Device.

RTU
A single-use rectal unit, and an acronym for what was previously referred to as the Rectal Thermal Unit.

RTU Plus
The rectal unit with a reusable handle and single-use balloon.

Standard mode
Select standard mode from the Control Panel on the Urologix® - BPH Treatment screen to adjust treatment parameters (urethra setting and treatment time) during a Cooled ThermoTherapy™ procedure in automatic treatment mode.

Startup routine
The CoolWave Control Unit internal checking procedure, which runs each time the system is turned ON.

Status Panel
Treatment data at the top of the Urologix - BPH Treatment screen: microwave power, coolant temperature, rectal temperature, urethra temperature, treatment status, and treatment progress.

Targis® Microwave catheter
A type of microwave catheter.

Temperature sensor
A device within the microwave catheter that monitors the urethral temperature of the patient; or a device within the rectal unit that monitors the rectal temperature of the patient.

Testes
The male reproductive glands that reside in the scrotum and produce spermatozoa. Interstitial cells in the testes secrete a hormone, an androgen, that aids the growth and development of the prostate gland.

Touchscreen monitor
The 15" diagonal color display with a touch sensitive glass covering. A gloved or ungloved finger can activate the touchscreen: a pen or stylus will not.

Transport Kit
The only FDA-approved method, other than the original shipping crate, for transporting a CoolWave® Control Unit. It includes a trolley and electrical safety tester.

Transrectal ultrasound (TRUS)
Procedure where a clinician inserts a probe into the rectum to obtain an image of the prostate. This image appears on the display to assist the clinician in placing a biopsy needle.

Transurethral incision (TUIP)
A surgical procedure that widens the urethra by making small cuts in the prostate and the bladder neck where the bladder and urethra join.

Transurethral resection (TURP)
A surgical procedure that involves the removal of tissue from the interior of the prostate with an instrument called a resectoscope.

Treatment parameters
CoolWave Control Unit values, such as the microwave catheter and the rectal temperatures, that the clinician monitors during treatment.

Treatment protocol
The step-by-step plan the clinician follows when treating the patient’s prostate condition. Or, the set of treatment parameters clinicians choose to treat a patient’s prostate condition.

Treatment session
A treatment session begins when the patient enters the clinic and ends when the treatment is over and he is discharged.

Treatment timer
The mechanism in the CoolWave® Control Unit that advances increments of seconds and minutes at therapeutic temperature.

TRUS
An acronym for transrectal ultrasound.

TUIP
An acronym for transurethral incision of the prostate.

TURP
An acronym for the transurethral resection of the prostate.

Universal Precautions Guidelines
A standard set of safeguards that apply to patients undergoing treatment. For example, the CoolWave Control Unit should not be moved while the electrical cord is connected to a power source.

Urethra set point
The urethra temperature the Control Unit maintains during a treatment. The system increases or decreases microwave power until it reaches the urethra set point.

Urethra temperature
The temperature at the tip of the microwave catheter in the center of the treatment region.

Urinary tract
The pathway in the urogenital system that urine travels as it is eliminated from the body. It consists of the renal tubules and pelvis of the kidney, the ureter, the bladder, and the urethra.

Urination
Discharge of liquid waste from the body.

USB flash drive
A Universal Serial Bus (USB) flash drive is a portable storage device that plugs into a computer USB port.

Verumontanum
An elevation in the floor of the prostate gland where it joins the urethra and the entrance of the seminal ducts.

5.6 Electromagnetic Compatibility (EMC) Tables

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration - Electromagnetic Emissions</th></tr>
<tr><td colspan="3">The Targis® System with CoolWave® Control Unit is intended for use in the electromagnetic environment specified below. The customer or the user of the Targis System with CoolWave Control Unit should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions Test</th><th>Compliance</th><th>Electromagnetic Environment - Guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 2</td><td>The Targis System with CoolWave Control Unit must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.</td></tr>
<tr><td>RF emissions
CSPR 11</td><td>Class A</td><td rowspan="3">The Targis System with CoolWave Control Unit is suitable for use in all establishments other than domestic and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies building used for domestic proposes, provided that the following warning is heeded:

Warning: This equipment is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures such as re-orienting or relocating the Targis System with CoolWave Control Unit or shielding the location.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/
flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Table 5-2 Electromagnetic Emissions

Guidance and manufacturer's declaration - Electromagnetic Immunity			
The Targis® System with CoolWave® Control Unit is intended for use in the electromagnetic environment specified below. The customer or the user of the Targis System with CoolWave Control Unit should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle <40% U_T (>60% dip in U_T) for 5 cycles <70% U_T (>30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle <40% U_T (>60% dip in U_T) for 5 cycles <70% U_T (>30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Targis System with CoolWave Control Unit requires continued operation during power mains interruptions, it is recommended that the Targis System with CoolWave Control Unit be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is an A.C. mains voltage prior to application of the test level			

Table 5-3 Electromagnetic Immunity

Guidance and manufacturer's declaration - Electromagnetic Immunity			
The Targis® System with CoolWave® Control Unit is intended for use in the electromagnetic environment specified below. The customer or the user of the Targis System with CoolWave Control Unit should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	**Electromagnetic Environment - Guidance**
Portable and mobile RF communications equipment should be used no closer to any part of the Targis System with CoolWave Control Unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
			Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3V	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5 GHz	3V/m	$d = 1.2\sqrt{P}$ 80MHz to 800 MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5GHz
Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strength from fixed RF transmitters, as determined by an electromagnetic site survey*, should be less than the compliance level in each frequency range.** Interference may occur in the vicinity of equipment marked with the following symbol:			
Note 1. At 80 MHz and 800 MHz, the higher frequency range applies Note 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
* Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength in the location in which the Targis System with CoolWave Control Unit is used exceeds the applicable RF compliance level above, the Targis System with CoolWave Control Unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Targis System with CoolWave Control Unit.			
** Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m			

Table 5-4 Electromagnetic Immunity (continued)

Recommended separation distance between portable and mobile RF communications equipment and the Targis® System with CoolWave® Control Unit

The Targis System with CoolWave Control Unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Targis System with CoolWave Control Unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Targis System with CoolWave Control Unit as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Table 5-5 Recommended Separation Distances

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CE 0086

CoolWave® User Manual - Part #250023-001 Rev G, Jun-2010
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